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Zembic, A.

2019

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Anja Zembic

ISBN: 978-94-6323-474-0
Author & Lay-Out: Anja Zembic
Cover: Anja Zembic & Ilse Modder, www.ilsemodder.nl
Print by: Gildeprint – Enschede, www.gildeprint.nl

VRIJE UNIVERSITEIT

Maxillary overdentures retained by two implants

ACADEMISCH PROEFSCHRIFT

ter verkrijging van de graad Doctor aan de
Vrije Universiteit Amsterdam,
op gezag van de rector magnificus prof.
dr. V. Subramaniam,
in het openbaar te verdedigen
ten overstaan van de promotiecommissie van de
Faculteit der Tandheelkunde
op vrijdag 8 februari 2019 om 11:45 uur in de
aula van de universiteit,
De Boelelaan 1105

door

Anja Zembic

geboren te Albstadt, Duitsland

Promotor:	Prof. dr. D. Wismeijer
Copromotoren:	Dr. A. Tahmaseb Eghbali Prof. dr. C.H.F. Hämmerle
Beoordelingscommissie:	Dr. T. Forouzanfar Prof. dr. F. Müller Prof. dr. G.J. Meijer Prof. dr. H.J.A. Meijer Prof. dr. I. Naert Prof. dr. M.A.J. van Waas

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Pars pro toto

To my family with infinite love

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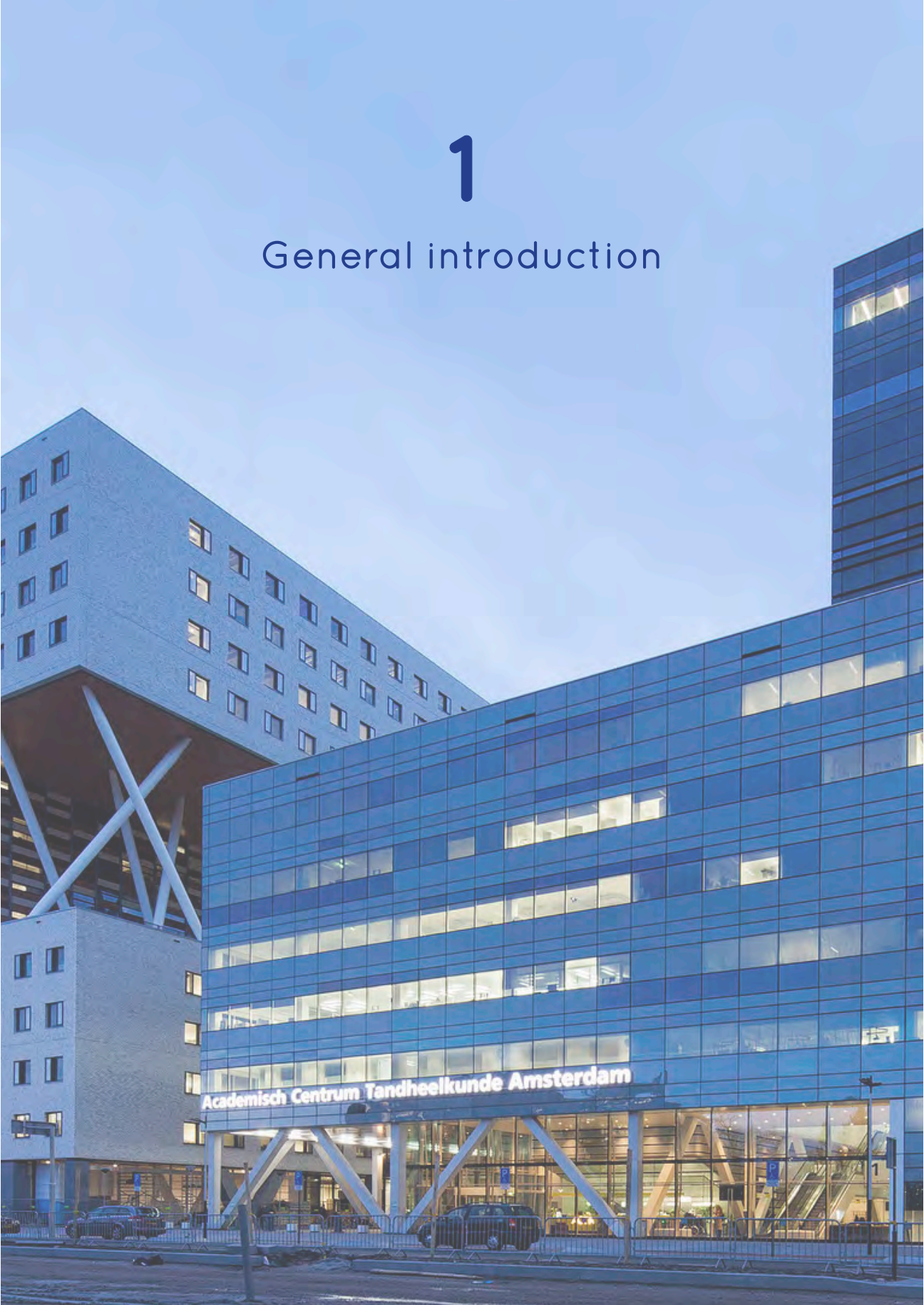
General introduction



1 General introduction

Edentulism is, according to the World Health Organization (WHO) classified as physical impairment and can have significant impact on the patient`s quality of life. Today, considering the prevalence of edentulous patients worldwide there is a great variation per region with decreasing numbers in general (Mojon et al. 2004; Osterberg et al. 1995; Petersen et al. 2005; Samson et al. 2008; Turkyilmaz et al.
2010). Still, taking into account the increase in life expectancy, in the future the treatment of the edentulous patient will remain a challenge (Christensen et al. 2009). As a consequence, patients are likely to be at an older age when loosing their remaining teeth with more complex bone morphologies due to advanced alveolar ridge resorption, cognitive impairement, deteriorated muscle control, xerostomia and sensitive mucosa as possible side effects from the medication (Muller 2014). This trend can be seen e.g. in Switzerland, with almost 40% of edentulous patients being
85+ years (Douglass et al. 2002; Zitzmann et al. 2008). This might explain that recent studies included patients of 85 years and older as “the elderly” (Muller 2014).

It has been demonstrated that patients and clinicians rate the quality of dentures differently (Awad et al. 2000; Heydecke et al. 2003). While clinicians focus on factors like survival, longevity and complication rate, patients prioritize aspects like benefit, cost effectiveness, social and psychological impacts.

When assessing the treatment outcome on the quality of life, the patient is the best judge and needs to be satisfied (Kaplan et al. 1993; Stephens et al. 1997). Previous studies on edentulous patients suggest that patient-based measures are more reliable than measures with regard to function (Awad et al. 2003; Feine et al. 1994). The assessment of the patient`s perception to oral health, the so-called Patient Reported Outcome Measures (PROMs), have gained significant importance in the dental literature accordingly (De Bruyn et al. 2015; Wiklund 2004).

A comprehensible means to assess the oral health-related quality of life (OHrQoL) is the Oral Health Impact Profile (OHIP) (Strassburger et al. 2004). Thereby, seven domains possibly being affected by the prosthetic treatment are assessed. These comprise the ability to chew (functional limitation), physical pain, self-consciousness (psychological discomfort), the possibility to chew certain foods (physical disability), the feeling of embarrassment (psychological disability), the difficulty doing jobs (social disability) and the inability to function (handicap).

Implant overdentures significantly improve patient satisfaction, retention, function, comfort and quality of life for edentulous patients (Bouma et al. 1997; Strassburger et al. 2006; Wismeijer et al. 1997; Zembic & Wismeijer 2014).

Taking into account the economic situation today, it is essential to know the scientifically proven minimum number of implants needed to support or retain an overdenture to make this treatment option available to more patients.

Theoretically and from a biomechanical point of view, a higher number of implants might better support heavy functional loads, especially in situations with thin buccal bone (Rodriguez et al. 2000). Interestingly, no benefit was found at 10 years for 4 over 2 splinted implants in the edentulous mandible in terms of implant survival, bone loss, amount of aftercare and patient satisfaction (Meijer et al. 2009). Several prospective studies showed successful treatment outcomes for 2 mandibular
implants (splinted or unsplinted) retaining an overdenture up to 12 years of function (Davis & Packer 1999; Sadowsky 2001; van Steenberghe et al. 2001). Based on the huge amount of evidence an overdenture on 2 implants is suggested to be the standard procedure of care for the edentulous mandible (Feine et al. 2002).

For reasons of cost-effectiveness, even an overdenture on 1 implant may be an eligible option in geriatric patients towards a denture and showed improvements of comfort and function at 5 years with no implant loss (Cordioli et al. 1997). When compared to 2 implants, there was no significant difference in patient satisfaction, implant and prosthesis survival between overdentures retained by 1 or 2 implants at 3 and 5 years (Bryant et al. 2015; Gonda et al. 2010).

In the past, high numbers of implants were used for rehabilitation of the edentulous maxilla with overdentures. The implant survival rate amounted to 98% per year for six or more implants being splinted with a bar (Raghoebar et al. 2014). When 4 and 6 implants were compared in a randomized controlled trial, no significant differences were found for bone resorption (0.50 ± 0.37 mm vs. 0.52 ± 0.43 mm) and implant survival rates (100% vs. 99%) at 5 years (Slot et al. 2016). Thus, 4 implants are sufficient as retention for a maxillary overdenture. Considering the trend of patients becoming edentulous at an older age, less invasive treatment opportunities are gaining importance (Thomason et al. 2003). Especially as patient satisfaction was found to be independent of the number of implants in maxillary implant overdentures (De Bruyn et al. 2015). In general, there is a lack of evidence to define the ideal number of implants for the edentulous maxilla (Roccuzzo et al. 2012).

Furthermore, there is little scientific evidence on less than 4 maxillary implants as overdenture retention and the research focus should be targeted on straightforward, little invasive and cost-effective treatment options. Referring to the well-established treatment option of 2 implants in the mandible, the question to be answered then comes up, whether the same successful outcomes can be achieved for 2 implants in the edentulous maxilla.

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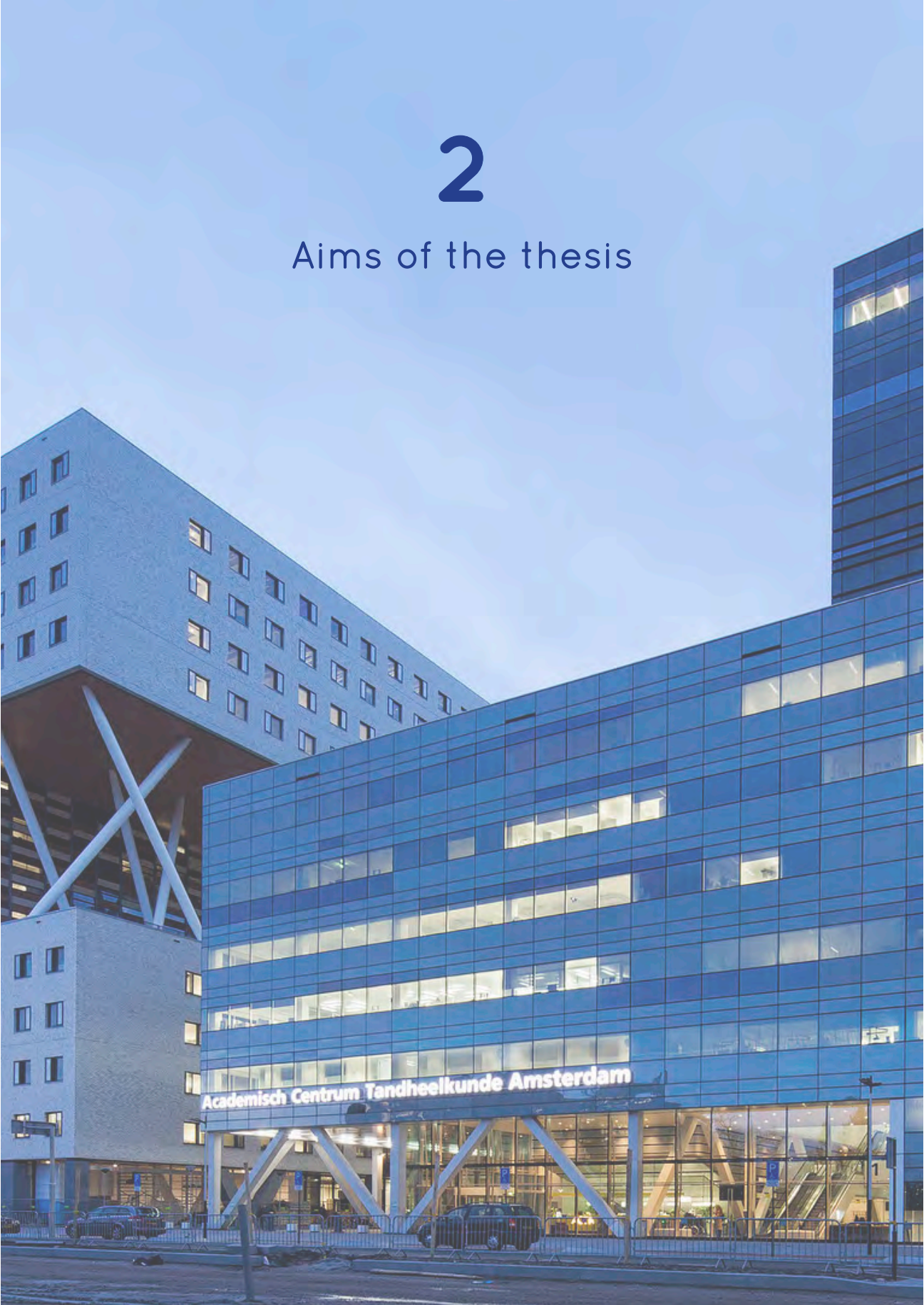
Aims of the thesis



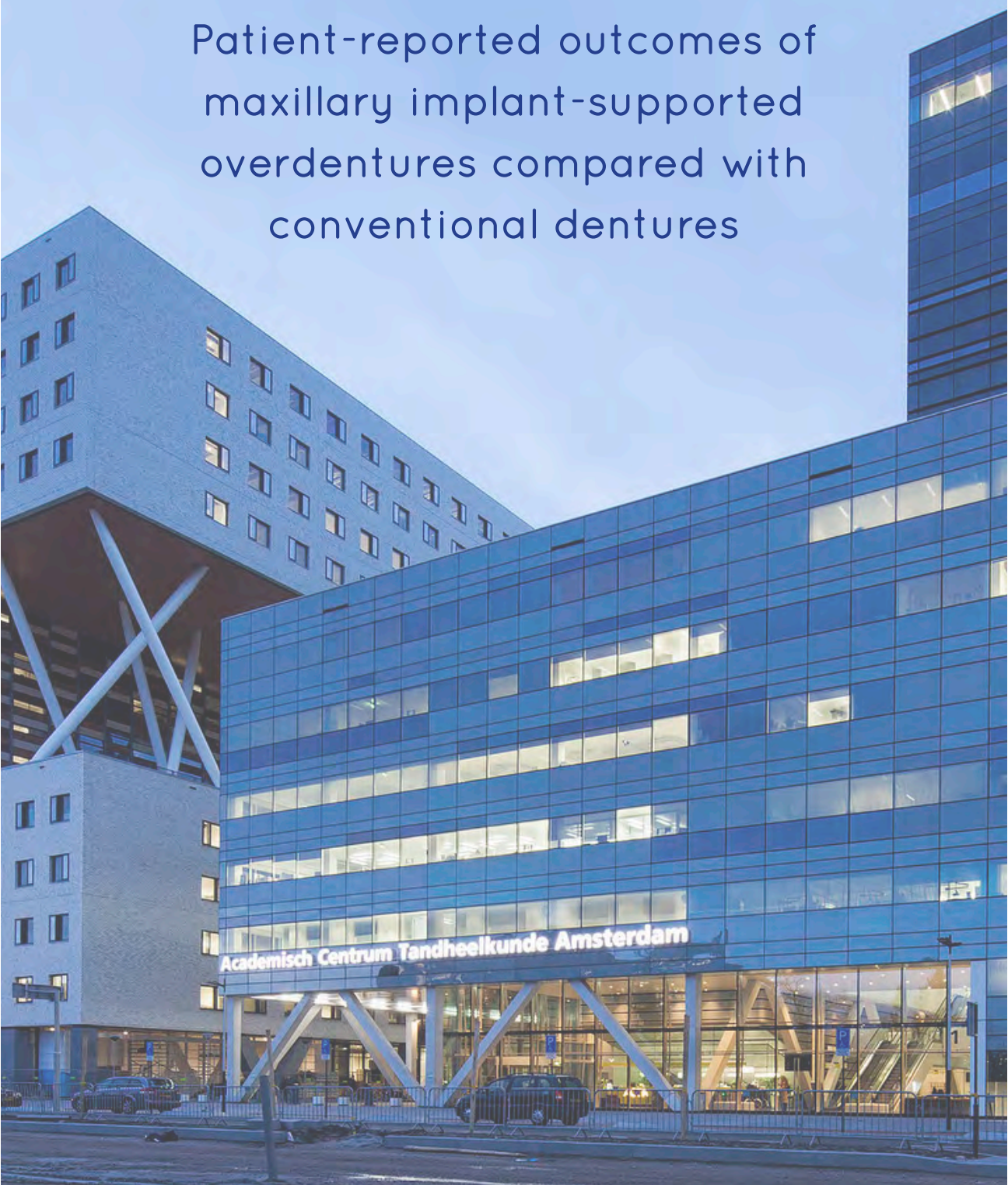
2 Aims of the thesis

The primary aim of the research described in the present thesis was to examine different aspects of maxillary overdentures retained by 2 implants. In detail, it was aimed at the following:

- to compare patient-reported outcome measures by means of the OHIP for maxillary conventional dentures and maxillary implant-retained overdentures (chapter 3)
- to evaluate the impact of the palatal coverage of implant-retained overdentures on patient satisfaction by means of the OHIP (chapter 4)
- to assess the clinical 1-year results of maxillary overdentures retained by 2
- implants including implant survival rates and peri-implant bone loss (chapter 5)
- to investigate the treatment effect of implant-retained maxillary overdentures on patient satisfaction over time, i.e. until 4 years of function (chapter 6)
- to analyze the clinical outcomes and bone levels at 4 years for 2 implants
- retaining a maxillary overdenture (chapter 7)

3

Patient-reported outcomes of maxillary implant-supported overdentures compared with conventional dentures



CLINICAL ORAL IMPLANTS RESEARCH

Anja Zembic
Daniel Wismeijer

Patient-reported outcomes of maxillary implant-supported overdentures compared with conventional dentures

Authors' affiliations:
Anja Zembic, Daniel Wismeijer, Department of Oral Implantology and Prosthetic Dentistry, Academic Center for Dentistry Amsterdam (ACTA), Amsterdam, The Netherlands
Anja Zembic, Division of Fixed Prosthodontics, School of Dental Medicine, University of Bern, Bern, Switzerland

Corresponding author:
Dr. Anja Zembic
Department of Oral Implantology and Prosthetic Dentistry, Academic Centre for Dentistry Amsterdam (ACTA), Gustav Mahlerlaan 3004, 1081 LA Amsterdam, The Netherlands
Tel.: +31 020 598 04 12
Fax: +31 020 598 03 33
e-mail: a.zembic@acta.nl

Key words: jaw, edentulous, maxilla, quality of life, dental implants, denture, complete, patient satisfaction, dentures, dental prosthesis, implant-supported

Abstract

Objective: The aim of the present prospective clinical study was to compare patient-reported outcomes for maxillary conventional dentures and maxillary implant-supported dentures.

Material and methods: Twenty-one patients (6 women and 15 men) being edentulous in the maxilla and encountering problems with their existing dentures were included. Twelve patients (4 women and 8 men) received a new set of conventional dentures, due to insufficient dentures. In nine patients (2 women and 7 men), the existing dentures were adjusted by means of relining or rebasing. All patients received implant-supported dentures on two retentive anchors. In total, 42 implants were inserted in the anterior maxilla. The participants rated their satisfaction on their existing conventional dentures, 2 months after insertion of new conventional dentures and 2 months after insertion of implant-supported dentures. Thereby, patients responded to questionnaires capturing the oral health impact profile (OHIP) using visual analog scales. Seven domains (functional limitation, physical pain, psychological discomfort, physical, psychological and social disability and handicap) were assessed. Higher scores implied poorer patient satisfaction. In addition, the questionnaire involved the evaluation of cleaning ability, general satisfaction, speech, comfort, esthetics, stability, and chewing ability. Higher scores implied higher patient satisfaction.

Results: Patient satisfaction significantly increased for implant-supported dentures compared with old dentures in all seven OHIP subgroups, as well as for cleaning ability, general satisfaction, ability to speak, comfort, esthetics, and stability ($P < 0.05$). The comparison of new conventional dentures and implant-supported dentures revealed a statistically significantly increased satisfaction for functional limitation (difference of 33.2 mm), psychological discomfort (difference of 36.7 mm), physical disability (difference of 36.3 mm), and social disability (difference of 23.5 mm), ($P < 0.05$). Additionally, general satisfaction, chewing ability, speech, and stability significantly improved in implant-supported dentures ($P < 0.05$).

Conclusions: Within the limits of this study, maxillary dentures retained by two implants provided some significant short-term improvements over conventional dentures in oral- and health-related quality of life.

Date:
Accepted 6 March 2013

To cite this article:
Zembic A, Wismeijer D. Patient-reported outcomes of maxillary implant-supported overdentures compared with conventional dentures.
Clin. Oral Impl. Res. **00**, 2013, 1–10
doi: 10.1111/clr.12169

With today's high life expectancy and continuous population growth, the amount of elderly patients visiting the dental practice is increasing. For a proper treatment of these individuals, medical, social, and dental factors have to be considered. The incidence of edentulous patients varies worldwide between 7% and 69% (Petersen et al. 2005). Even though several authors stated a decreasing number of edentulous patients (Turkyilmaz et al. 2010; Furuyama et al. 2012), demographic trends show an immense increase in adults over 55 years of age (Douglass et al. 2002).

Given that oral health is strongly age-dependent, which explains that edentulous people are usually found to be 65 years or older (central bureau of statistics 2012, Den Haag, the Netherlands; DMS IV 2006), a high number of edentulous patients might be expected in private practice even in the future.

Thus, it is likely that more patients will become edentulous at an older age, where patients have a reduced adaptation to deal with the edentulous situation (Thomason et al. 2003).

Denture retention is by definition, resistance of a denture to vertical movement in

the opposite direction, away from the tissues (Jacobson & Krol 1983; Nairn & Shapiro 1995). Several factors contribute to retention, such as psychological acceptance, adhesion, cohesion, viscosity, gravity, oral and facial musculature, vacuum and atmospheric pressure (Roessler 2003). A relatively high number of patients wearing mucosa-supported dentures are likely to be dissatisfied, mostly with their mandibular dentures (Lechner & Roessler 2001). Mostly, these patients complain about lack of prosthesis stability and/or retention and decreased chewing ability (van Waas 1990b). The patients are hindered when speaking and eating which in turn has its impact on their well-being. In the past, some patients even accepted denture problems as part of wearing a prosthesis (MacEntee et al. 1997).

The introduction of implants to retain dentures was a huge improvement for those patients and offered new treatment alternatives. Different aspects, such as psychological factors, mastication, stability, comfort, speech, food choice and impact on social activities could be optimized (de Grandmont et al. 1994; Bouma et al. 1997; Wismeijer et al. 1997; Awad & Feine 1998; Awad et al. 2003a,b; Heydecke et al. 2003; Strassburger et al. 2004; Allen et al. 2006).

Historically, implants supporting overdentures in the maxilla performed inferior to implants supporting overdentures in the mandible (Engquist et al. 1988; Naert et al. 1991; Jemt et al. 1992, 1996; Johns et al. 1992; Quirynen et al. 1992; Smedberg et al. 1993; Palmqvist et al. 1994; Hutton et al. 1995; Ekfeldt et al. 1997; Bergendal & Engquist 1998). In addition, the success rates for maxillary implants vary quite extensively among the studies (Engquist et al. 1988; Jemt et al. 1992, 1996; Johns et al. 1992; Kramer et al. 1992; Smedberg et al. 1993). A number of parameters might possibly explain these differences, including number and length of implants, prosthesis design, bone quality and quantity and opposing dentition (Sadowsky 2007). It was also demonstrated that two implants supporting overdentures in the maxilla could not be recommended due to considerable bone loss observed in a 4-year retrospective study (Quirynen et al. 1991). More favorable outcomes, however, were observed when the number of implants was increased to four and the implants rigidly splinted (Naert et al. 1998; de Albuquerque Junior et al. 2000). Therefore, four splinted implants were considered to be the minimal number of implants to support overdentures in the maxilla. This treatment concept was based on the use of implants with a smooth surface.

Over the years, implant surfaces have changed and improved leading to more favorable implant survival rates also in the maxilla (Del Fabbro et al. 2004; Oliveira et al. 2012). Therefore, the minimal and optimal number of implants to support maxillary overdentures has regained scientific attention and is not yet defined (Kronstrom et al. 2006). In addition, there is a controversy with concern to the best prosthetic treatment option for edentulous patients (Burns 2000; Feine et al. 2002; Fitzpatrick 2006; Strassburger et al. 2006; Klemetti 2008). For this purpose, not only the clinician's evaluation of the reconstruction is needed, but also the patient's individual perception and satisfaction is decisive (Feine et al. 1998). The assessment of oral health is thereby a comprehensive means to rate the patient satisfaction (John et al. 2004a,b,c; Strassburger et al. 2006). The oral health-related quality of life (OHRQoL, Oral Health-Related Quality of Life) describes different aspects of life being affected by the oral health. These include the ability to function (biting, chewing, and speaking), psychological status (self-esteem, satisfaction with appearance), social factors and pain or discomfort (Inglehart & Bagramian 2002).

The OHRQoL is assessed by means of patient questionnaires capturing the Oral Health Impact Profile (OHIP; Slade & Spencer 1994; Locker 1995). Being introduced in the 1990s, the OHIP is now translated in several languages and is one of the most comprehensive means used worldwide to evaluate patient satisfaction (Slade & Spencer 1994). In this way, results of studies reporting on patient satisfaction can be compared with each other, which will help define clinical guidelines and the most appropriate treatment option for the edentulous maxilla.

With regard to the edentulous mandible, there is a large body of evidence to support the use of implant-supported dentures on two implants on a regular basis (Mericske-Stern 1990; Wismeijer et al. 1997; Feine et al. 2002; Thomason et al. 2009). The results of a systematic review showed objective benefits in the masticatory performance of patients wearing implant-supported or retained dentures compared with conventional dentures (Fueki et al. 2007).

In contrast to the mandible, there is less scientific evidence for implant-supported maxillary dentures with regard to implant survival, biological, technical and prosthetic parameters and patient-reported outcomes (Gallucci et al. 2009; Andreiotelli et al. 2010; Stoumpis & Kohal 2011). Furthermore, little attention has been paid to patient satisfaction for maxillary overdentures compared with implant-supported overdentures. Comparisons with alternative treatment strategies such as complete overdentures are thus strongly needed (Allen & McMillan 2003).

A straightforward, minimal-invasive and cost-effective treatment option for the edentulous maxilla could be the placement of two implants. Thereby, the retention of the denture could be sufficiently improved for patients experiencing problems with prosthesis retention.

The hypothesis is that patient satisfaction and prosthesis retention will be enhanced by the use of two implants to support a maxillary denture compared with a conventional maxillary denture.

The aim of the present prospective clinical study was to compare patient-reported outcomes for maxillary conventional dentures and maxillary implant-supported dentures.

Materials and methods

Study design

The present study was designed as a within-subject prospective clinical trial. The local ethical committee approved the study protocol and procedures. Patients were thoroughly informed about the study aim and the procedures. Written informed consent was obtained from all patients prior to the beginning of the study.

Patients

Patients were consecutively referred by private practitioners responding to a letter of inquiry sent to them with the information on the intended study purpose. All patients were treated at the Academic Center for Dentistry Amsterdam (ACTA), Amsterdam, the Netherlands.

The following inclusion criteria were applied:

- edentulism in the maxilla for at least 1 year,
- patients wearing definitive dentures for at least 6 months,
- patients encountering problems with the existing dentures and in need of implant treatment,
- good general condition,
- all ridge resorption patterns were allowed in the anterior maxilla, provided that the implant could be placed primary stable and was mostly embedded in autologous

bone (classification according to Cawood & Howell 1988),
- edentulous patients in the mandible or patients having up to a maximum of four abutments (either on teeth or on implants)both smokers (with a limit of 10 cigarettes per day) and nonsmokers were included.

The applied exclusion criteria were as follows:
- patients with immediate maxillary dentures,
- patients with clinical signs of bruxism or other severe functional disorders,
- Patients with a systemic condition jeopardizing successful implant therapy,
- Disorders in the area of planned implant placement, such as chronic bone diseases, present or previous tumors or irradiation,
- Lack of compliance.

Fig. 1. Patient with functionally and esthetically insufficient old conventional dentures (picture left) and after insertion of new conventional dentures (picture right).

One-hundred and forty patients were screened clinically for possible inclusion in the present study. An initial clinical and radiographic examination (panoramic radiograph) was performed. Thereby, the quality of the existing dentures was assessed, and the conditions of the oral mucosa and the bone support were evaluated. Forty patients fulfilled the requirements for the present study and were included for further screening.

In case, the dentures fulfilled functional and esthetic criteria with only minor deviations, the existing dentures were adjusted (e.g. relining and rebasing), to provide the patients with the most appropriate prostheses (Zarb & Jacob 2004).

In case, the existing dentures were insufficient with regards to function, esthetics and/or other parameters, new dentures were made according to proven standards for overdentures (Fig. 1; Anderson 2004; Bolender 2004; Davis 2004a,b; Fenton 2004; Zarb & Finer 2004). Thus, there were two groups of patients for conventional dentures: patients with old conventional dentures, that is, adjusted existing dentures (OP) and patients receiving new conventional dentures (NP). Within this study, all patients received implant-supported dentures, which was the third group (IP; Zarb et al. 2004). Oral hygiene instructions were given specifically for denture wearers.

The adjusted or new maxillary overdentures served as a master for the fabrication of a replica prosthesis (a scan template) with barium sulfate. A cone beam computed tomography (CBCT)-scan (NewTom 5G, QR, Verona, Italy) was performed and the bone quantity evaluated according to the Cawood and Howell classification of ridge resorption (Cawood & Howell 1988). Patients with sufficient bone in the anterior maxilla were considered for participation in the present study. As a result, 21 patients in total were finally included for participation.

Surgical and prosthodontic procedures

The surgeries were all performed by one experienced surgeon (AZ). Two implants were placed in the anterior maxilla, preferably in the canine area and by means of guided surgery (Roxolid® and coDiagnostiX, Institut Straumann AG, Basel, Switzerland). The canine position was defined by the denture. Thus, the implants were placed in a nonstandardized interabutment distance. In case of minor bone defects, GBR procedures not compromising primary implant stability were applied. In this case, the healing pattern was submerged, and in all other cases, the healing was performed transmucosal. Following implant placement, the patients were instructed not to wear the dentures for 1 week. At the 1-week control, the dentures were grinded out thoroughly in the implant area and in some cases relined with soft denture conditioner (Soft-Liner, GC corporation, Tokyo, Japan). In case of submerged healing, abutment connection was performed after a healing period of 4 months. Implant impressions were performed 1 week after abutment connection. In case of transmucosal healing, implant impressions were performed 2 months after implant placement. Thus, in all patients, conventional loading was performed (Esposito et al. 2007).

At the day of impression, the final maxillary denture was used as an individual tray and to register the intermaxillary relation simultaneously (Batenburg et al. 1993) (Fig. 2). For that purpose, two access holes were grinded at the location of the implants. Implant impression copings (RN synOcta® impression cap, Institut Straumann AG) were shortened by the dental technician to perform the impression in full occlusion even in cases of limited intermaxillary space (Figs 2 and 3). In cases with sufficient vertical space, impression copings of regular length were used. The impression copings were screwed onto the implants. Their positions were changed if the radiograph revealed a misfit. Subsequently, an open tray implant impression was performed with the patient in an upright position and with the teeth in full occlusion. The impression was performed using a polyether material (Impregum, 3M Espe, Seefeld, Germany). The bite registration was made with a silicone material (Futar® D Fast, Kettenbach GmbH & Co. KG, Eschenburg, Germany). The denture was then sent to the dental technician for modification and incorporation of a metal frame as a backing in the anterior

Fig. 2. Illustration of the closed mouth reline impression, facilitating simultaneous jaw record relationship (Batenburg et al. 1993).

part of each denture (Fig. 4). Acrylic denture teeth were used for all patients (Candulor PhysioStar® NFC+, Candulor AG, Wangen, Switzerland). The occlusal scheme was lingualized, balanced and without anterior contacts (Wismeijer et al. 1995; Kim et al. 2005). During this time period, the patient was wearing a provisional maxillary denture, which was fabricated as a duplicate of the existing one. At the time of insertion of the modified implant-supported denture, two titanium retentive anchors with a height of 3.4 mm (Retentive anchor abutment, Institut Straumann AG) were screwed onto the implants with a defined torque of 35 Ncm (according to the manufacturer's recommendations). Two titanium matrices were polymerizen into the denture base by the dental technician (Titanium matrix for retentive anchor, Institut Straumann AG). The patients were instructed how to handle and clean their dentures and soft tissues properly. Regular follow-up visits were performed at 1, 2, 4, 8 and 16 weeks postinsertion of the denture. At all examinations, mucosa conditions and the presence of technical complications (loss of retention, fracture of denture or attachments) were assessed. In addition, the occlusion was controlled and corrected, to be balanced and without anterior contacts in habitual occlusion (Horn & Stuck 1987). A lingualized occlusion was realized in all patients (Lang & Razzoog 1992).

Fig. 3. Shortened implant impression copings with adjusted screw head.

Fig. 4. Implant-retained maxillary denture with metal frame, occlusal and basal view.

Patient-reported outcomes

The OHIP-20E questionnaire in Dutch language was used as outcome measure for different treatments of the edentulous maxilla. The 20 questions are summed up in seven domains (functional limitation, physical pain, psychological discomfort, physical, psychological and social disability and handicap), which cover a wide range of possible oral health problems that have an impact on quality of life. The anchor words were "none" and "severe." Higher scores implied poorer patient satisfaction.

In addition, the questionnaire involved the evaluation of cleaning ability, general satisfaction, speech, comfort, esthetics, stability, and chewing ability. To assess the chewing ability, the patients rated the chewing of different types of food (soft bread, hard cheese, dry sausage, lettuce, raw apple, and carrot). The different foods were defined from a list of foods ranked in order of masticatory difficulty for patients with complete dentures (Bergman & Carlsson 1972; Feine et al. 1994). The anchor terms for evaluation were "completely satisfied" and "completely dissatisfied." Higher scores implied higher patient satisfaction with exception of the evaluation of speech, where higher scores expressed a decrease in patient satisfaction.

All participants measured their satisfaction and perception of the dentures by responding to questionnaires using visual analog scales (VAS; de Grandmont et al. 1994). The VAS consisted of a 100 mm horizontal line, which was confined at both ends with the abovecited anchor words. The patients were asked to draw a vertical line anywhere across the horizontal line, where their perception was best represented.

First, the patients rated their existing conventional dentures prior to the start of the treatment. Subsequently, the procedure was repeated for patients receiving new dentures 2 months after the insertion of the new denture. The time period of 2 months was previously defined as an adequate time period for patients to adapt and rate the new dentures (de Grandmont et al. 1994). Finally, all patients completed another VAS questionnaire 2 months after insertion of the implant-supported maxillary denture.

Statistical analysis

Standard statistics were applied calculating means and standard deviations of patient-reported outcomes for old dentures, new dentures and implant-supported dentures. The analysis was performed using a statistical software program (SAS®Version 9.2, SAS Insitute Inc. Cary, NC, USA). Before and after treatment measurements were analyzed with the Wilcoxon matched pairs signed rank test (PROC UNIVARIATE). To detect the differences between the treatment modalities the Wilcoxon Mann–Whitney *U*-test was applied (PROC NPAR1WAY). The overall chewing ability was calculated using the average value of their subgroups (chewing ability of different types of food). The level of significance chosen in all statistical tests was set at 5%.

Results

Patients

Twenty-one patients (6 women and 15 men) with a mean age of 63 years (range 52–81 years) fulfilled the inclusion criteria. Seven patients (1 woman and 6 men) were smokers, and 14 patients (5 women and 9 men) were nonsmokers. Twelve patients (4 women and 8 men) received a new set of conventional dentures. In the remaining nine patients (2 women and 7 men), the existing dentures fulfilled functional and esthetic criteria and were adjusted by means of relining or rebasing, if necessary. Thus, in these patients, no new dentures were made.

The opposing dentitions composed of seventeen patients with mandibular implant-supported dentures (16 patients had 2 implants and a bar, 1 patient had 3 implants and a bar and 1 patient had 2 implants and retentive anchors), three patients with conventional mandibular dentures and one patient with three remaining natural teeth and a frame denture. In total, 42 implants (Standard Roxolid® implants, Institut Straumann AG) were inserted in the anterior maxilla and reconstructed with retentive anchors (Retentive anchor abutment, Institut Straumann AG). In total, 36 implants were placed flapless, and six implants were placed with simultaneous GBR procedures.

Patient-reported outcomes

The mean values of the OHIP domains (in mm) with standard deviations for old conventional (OP), new conventional (NP) and implant-supported dentures (IP) are presented in Table 1. A gradual increase in patient satisfaction (represented by decreasing VAS values) was evident for new conventional and implant-supported dentures (compared with old conventional dentures).

The lowest rating (greatest satisfaction) was observed for social disability from patients wearing implant-supported maxillary dentures (OHIP score 6.7; SD 13.3). This was 21.3 mm

Table 1. **Mean values (mm) and standard deviations of all OHIP subgroups for old (OP), new (NP) and implant-retained dentures (IP)**

	OP mean		NP mean		IP mean	
OHIP subgroups	*N* = 19	OP SD	*N* = 12	NP SD	*N* = 21	IP SD
Functional limitation	65.5	28.9	43.8	36.0	18.1	16.0
Physical pain	57.3	26.3	29.7	25.6	11.7	14.4
Psychological discomfort	55.1	33.0	40.6	32.8	14.6	17.1
Physical disability	50.3	24.8	40.8	32.9	12.9	15.9
Psychological disability	48.9	30.3	26.9	36.2	13.3	20.6
Social disability	28.0	29.7	25.4	28.7	6.7	13.3
Handicap	30.2	31.7	32.4	40.8	10.0	14.5

Table 2. **Difference of VAS values (mm) for OHIP subgroups (mean values and standard deviations) for old (OP) dentures compared with implant-retained dentures (IP). Wilcoxon matched pairs signed rank test applied**

OHIP subgroups	Mean difference OP to IP	SD of difference OP to IP	Median difference OP to IP	*P*-value	*N*
Functional limitation	−47.8	35.4	−54.3	<0.01	18
Physical pain	−46.1	35.7	−58.4	<0.01	18
Psychological discomfort	−39.7	37.4	−39.7	<0.01	18
Physical disability	−37.5	33.7	−39.9	<0.01	18
Psychological disability	−36.3	42.2	−45.2	<0.01	17
Social disability	−20.9	32.7	−12.6	<0.01	17
Handicap	−19.5	30.9	−13.8	<0.01	17

Table 3. **Patient satisfaction (mm; mean values and standard deviations) for general variables of old (OP), new (NP) and implant-retained dentures (IP)**

	OP mean		NP mean		IP mean	
Variables	*N* = 19	OP SD	*N* = 12	NP SD	*N* = 21	IP SD
Cleaning ability	83.1	25.2	92.0	9.0	86.1	14.1
General satisfaction	33.7	27.5	63.0	29.6	84.0	22.1
Ability to speak	53.3	35.9	62.2	29.2	26.9	33.9
Comfort	33.2	26.2	65.2	23.5	75.0	31.8
Esthetics	58.6	35.9	76.5	20.1	83.7	22.9
Stability	39.1	33.0	57.2	31.9	73.0	32.4
Chewing ability	32.4	28.5	50.7	28.0	74.2	20.3

Table 4. **Difference of VAS values (mm) for general variables (mean values and standard deviations) for old (OP) dentures compared with implant-retained dentures (IP). Wilcoxon matched pairs signed rank test applied**

Variables	Mean difference OP to IP	SD of difference OP to IP	Median difference OP to IP	*P*-value	*N*
Cleaning ability	3.0	32.1	−3.1	0.66	19
General satisfaction	50.3	32.4	60.2	<0.01	19
Ability to speak	−29.6	58.9	−46.9	0.04	18
Comfort	41.4	33.8	41.1	<0.01	18
Esthetics	25.1	38.5	13.3	0.02	19
Stability	31.9	42.7	45.9	0.01	18
Chewing ability	41.8	25.8	43.8	<0.01	19

Table 5. **Difference of VAS values (mm) for OHIP subgroups (mean values and standard deviations) for new (NP) dentures compared with implant-retained dentures (IP). Wilcoxon matched pairs signed rank test applied**

OHIP subgroups	Mean difference NP to IP	SD of difference NP to IP	Median difference NP to IP	*P*-value	*N*
Functional limitation	−33.2	34.2	−28.6	0.04	8
Physical pain	−22.0	26.9	−15.9	0.05	8
Psychological discomfort	−36.7	29.6	−35.2	0.02	8
Physical disability	−36.3	35.4	−21.2	0.02	8
Psychological disability	−24.2	34.8	−10.0	0.16	7
Social disability	−23.5	27.4	−6.0	0.04	7
Handicap	−25.1	33.2	−2.5	0.06	7

less than the ratings from patients wearing old conventional dentures and 18.7 mm less than the ratings from patients wearing new conventional dentures.

The highest rating (lowest satisfaction) was scored for functional limitation in patients wearing old conventional dentures (OHIP score 65.5; SD 28.9). Thereby functional limitation was rated 21.7 mm higher than with new conventional dentures and 47.4 mm higher than for implant-supported dentures.

When comparing old and implant-supported dentures, there was a significant increase in patient satisfaction with regard to all 7 OHIP subgroups for implant-supported dentures (Table 2; $P < 0.05$). Patient satisfaction was highest for implant-supported dentures (lowest VAS scores). When comparing the general variables (cleaning ability, general satisfaction, ability to speak, comfort, esthetics, stability, and chewing ability) for old and implant-supported dentures, there were significantly better results (higher scores) for implant-supported overdentures for all parameters, except cleaning ability (Tables 3 and 4).

The comparison of new conventional dentures and implant-supported dentures revealed a statistically significantly increased satisfaction for functional limitation (difference of 33.2 mm), psychological discomfort (difference of 36.7 mm), physical disability (difference of 36.3 mm), and social disability (difference of 23.5 mm), $P < 0.05$ (Table 5). Comparing new dentures with implant-supported dentures, general variables were rated significantly higher for implant-supported dentures for all parameters except cleaning ability, comfort and esthetics (Table 6).

Discussion

Significantly improved patient satisfaction was found for maxillary implant-supported dentures in all OHIP subgroups, as well as for general satisfaction, speech, comfort, esthetics, stability, and chewing ability compared with old dentures.

Slightly less parameters improved significantly when new dentures were compared with implant-supported ones. Social disability improved most significantly (greatest satisfaction) with implant-supported maxillary dentures. Patients were significantly least satisfied with the functional limitation of old conventional dentures. Unlike the findings of the present study, a previous within-subject comparison did not find a significant

Table 6. **Difference of VAS values (mm) for general variables (mean values and standard deviations) for new (NP) dentures compared with implant-retained dentures (IP). Wilcoxon matched pairs signed rank test applied**

Variables	Mean difference NP to IP	SD of difference NP to IP	Median difference NP to IP	*P*-value	*N*
Cleaning ability	−0.4	10.2	−2.0	0.35	13
General satisfaction	22.0	24.6	26.0	<0.01	13
Ability to speak	−45.0	37.9	−54.0	<0.01	13
Comfort	11.1	39.8	15.0	0.15	13
Esthetics	7.8	34.8	13.3	0.13	13
Stability	21.8	39.3	21.9	0.04	13
Chewing ability	27.3	26.1	15.5	<0.01	13

improvement in general satisfaction, stability, retention, esthetics, mastication or speech with maxillary implant-supported prostheses compared with conventional maxillary prostheses (de Albuquerque Junior et al. 2000). In that study, four implants were splinted with a bar in contrast to the present study with two un-splinted maxillary implants. Furthermore, the opposing mandible was provided with fixed prostheses, whereas there were solely removable mandibular dentures (mostly on implants) in the present study. Thus, the patients compared maxillary implant-supported dentures to more advantageous conditions in the mandible than in the present study. This might explain the more critical appraisal toward implant-supported maxillary dentures on four implants and bar and the significantly stronger effect on the masticatory efficiency for maxillary dentures supported by two implants in the present findings (de Albuquerque Junior et al. 2000).

Interestingly, new conventional dentures were provided to all patients and like in the present study, questionnaires were filled in after an adaptation period of 2 months. It is thus assumable that patient satisfaction already increased through the application of new conventional dentures. The present results demonstrate this trend with less increased patient satisfaction for implant-supported dentures in patients wearing new conventional dentures compared to patients wearing adjusted old conventional dentures. This is substantiated by a systematic review where almost no significant improvement in general patient satisfaction, stability, retention, esthetics, mastication and speech was found for implant-supported maxillary dentures when patients were satisfied with their current maxillary conventional dentures (Sadowsky 2007).

The authors concluded that maxillary implant-supported prostheses should not be considered as a general treatment option for patients with good bone support (de Albuquerque Junior et al. 2000). Moreover, the authors do not support the use of maxillary implants in patients being satisfied with their conventional prostheses (de Albuquerque Junior et al. 2000). A randomized controlled clinical trial supports the finding that patients being satisfied with their current dentures have almost no significant improvement in general satisfaction when restored with implant-supported dentures (Heydecke et al. 2003). In the present study, the included patients had problems with their existing conventional dentures. Thus, a positive effect of the implants is plausible, independent of the bone conditions. The patients were less limited when eating with others and consequently the least disabled from a social aspect with implant-supported dentures. Several authors discussed the residual ridge height to be associated with masticatory efficiency (Gunne & Wall 1985; Lindquist et al. 1986; Slagter et al. 1992).

In the present study, most patients had good bone conditions, despite four patients exhibiting compromised bone situations. This contributed to the positive outcomes of implant-supported dentures.

Only little studies are available on maxillary dentures supported by two implants with rather poor results on implant survival rates and bone loss (Quirynen et al. 1991, 1992; Bergendal & Engquist 1998; Sanna et al. 2009). One study reported an absolute success rate of only 40% after a mean loading time of more than 6 years (Quirynen et al. 1992). Small numbers of patients were included in these studies and the results base mainly on smooth implant surfaces. In addition, no patient-reported outcomes were achieved comparing maxillary implant-supported dentures on two implants to conventional dentures. Thus, it is difficult to compare the results to the present study. One limitation of the present study is the differing number of VAS values due to incorrectly filled in questionnaires, despite detailed instructions. Only questionnaires with clear completion of the forms were considered for statistical analysis. Furthermore, the number of patients is rather small, even though being higher than in comparable studies on two maxillary implants (Quirynen et al. 1991; Bergendal & Engquist 1998; Sanna et al. 2009).

Promising results and high levels of patient satisfaction were found for maxillary dentures supported by four implants and a bar (Hooghe & Naert 1997; Naert et al. 1998; de Albuquerque Junior et al. 2000). Significant improvements for patient-reported outcomes regarding comfort, retention, function, esthetics, taste, speech, and self-esteem were reported in a study on maxillary dentures supported by 6–8 implants and a bar (Zitzmann & Marinello 2000). These authors concluded that implant-supported overdentures might be an equal and even more appropriate treatment option to fixed implant prostheses (Zitzmann & Marinello 2000). The high number of implants placed to support the removable dentures has to be considered though. A recent systematic review analyzed the number of implants needed to support maxillary overdentures (Klemetti 2008). On the basis of the available evidence, it was concluded that patient satisfaction and function were neither dependent on the number if implants nor on the attachment type (Klemetti 2008).

The ability to speak in the present study decreased after insertion of new conventional dentures but increased significantly with implant-supported dentures. The setup of anterior teeth of new conventional dentures was adjusted to photos demonstrating the previous natural tooth position. Thereby the tooth position in the anterior changed in most of the patients. This might have influenced the space for the tongue resulting in inferior speaking ability. Secondly, a certain time of adaptation is needed with new dentures. The patients thus had sufficient time to adapt to the new situation before insertion of implant-supported dentures, which were originally the converted conventional dentures. Consequently, there was no other change than the retention with implants. This might have contributed to the significant increase of the ability to speak with implant-supported dentures. This result is in agreement with a study where less speech problems were found after treatment with maxillary implant-supported dentures on a bar compared with fixed implant prostheses (Kronstrom et al. 2006).

The patients included in the present study were all edentulous for a certain period which makes it plausible that the cleaning ability did not improve with implant-supported

dentures but requires additional cleaning efforts. A study comparing maxillary implant-supported fixed and removable dentures found less problems with cleaning in patients with removable dentures and bar (Kronstrom et al. 2006).

In the present study, the implant-supported dentures did not change with respect to the appearance compared with the conventional dentures. Thus, there was no improvement with regard to the esthetics. The finding that stability improved significantly for implant-supported dentures compared with old and new conventional dentures in the present study is in agreement with several other studies (Boerrigter et al. 1995a,b; Wismeijer et al. 1997; Kapur et al. 1998). Based on a literature review, the positioning of implants in the anterior maxilla (mesial to the first premolars) enhances the stability of the overdenture, which is substantiated with the present results (Laurito et al. 2012). Also studies on mandibular overdentures retained by two implants provided significant improvements in stability in patients with severe problems adapting to conventional dentures and in medically compromised patients (Boerrigter et al. 1995a,b; Wismeijer et al. 1997; Kapur et al. 1998).

Conventional dentures can lead to relatively high degrees of OHRQoL in patients who have adapted well to the dentures (Allen et al. 2001). One has to bear in mind that the common ground of most of the previously mentioned studies, including the present one, is that the patients were denture wearers beforehand. Thus, an appropriate adaptation to edentulism and dentures was established prior to implant placement. As already mentioned, experienced the included patients denture problems (explaining the indication for implants and the highest scores for functional limitation). This is mirrored in several studies that found 25–80% of patients being unsatisfied with the function of their previous denture (Norheim & Valderhaug 1979; van Waas 1990a; Kaptein et al. 1998). The use of two implants in the maxilla is not a commonly accepted procedure and until today, there is no evidence with regard to an optimal number of implants to be placed when treating patients with an edentulous maxilla (Jemt et al. 1996; Ekfeldt et al. 2001; Kronstrom et al. 2006). On the basis of the present short-term results, the placement of two implants in the anterior maxilla seems to be sufficient for patient satisfaction and enhancement of prosthesis retention. One has to be cautious though not to generalize an implant-supported denture as treatment option of first choice for each edentulous situation.

The assessments of patient satisfaction 2 months after insertion of the dentures, might have affected patient's ratings in favor of the new treatment (new conventional dentures and implant-supported dentures). Therefore, patient satisfaction will again be analyzed after 1 year to evaluate the long-term effect.

In the present study, several factors (physical pain, psychological discomfort, handicap, cleaning ability, comfort, and esthetics) did not improve statistically significantly when a new conventional denture was compared with an implant-supported denture. A previous study found that patients who had problems with dentures and who received satisfactory new dentures showed improved chewing ability (Allen & McMillan 2002). Hence, certain improvements can be achieved simply by providing the patients with new dentures. Consequently, the present results illustrate that there was no significant improvement in comfort for maxillary implant-supported dentures compared with new dentures.

Furthermore, fully dentate patients becoming edentulous represent a special and challenging case for treatment and cannot be compared with patients wearing dentures for a longer period of time. These patients have to adapt first to the edentulous situation, are likely to experience more problems with dentures on two implants and were therefore not included in the present study.

On the basis of the present results, it is recommended to provide edentulous patients with adequate conventional dentures first, to allow for an appropriate denture adaptation. Especially in older patients, the process of adaptation takes time (Muller et al. 1995). In case, the patients are unsatisfied with the retention of their existing dentures even after an appropriate adaptation period, the placement of implants to retain the denture proved to be a suitable treatment option for enhancement of patient satisfaction.

Conclusion

The present results suggest that maxillary dentures retained by two implants provide significant short-term improvement over conventional dentures in oral- and health-related quality of life.

Acknowledgements: The authors would like to express their gratitude to PhD Ali Tahmaseb for his assistance in planning and conducting the surgeries. Moreover, many thanks go to Martin Bub and his team from the technical laboratory Zutphen in Zutphen, the Netherlands, for their sound efforts in creating the dentures. Further thanks go to the radiographic department for their uncomplicated and efficient support with the scans. In addition, many thanks to the undergraduate student Sirarpi Pogosian for her help with organizing the data and to Dr. Daniel S. Thoma and Walter Bürgin for their help and input in the statistical analysis.

This study was partly funded by the Academic Center for Dentistry Amsterdam (ACTA), the Netherlands. The implant material (implants and abutments) was supported by Institut Straumann AG, Basel, Switzerland.

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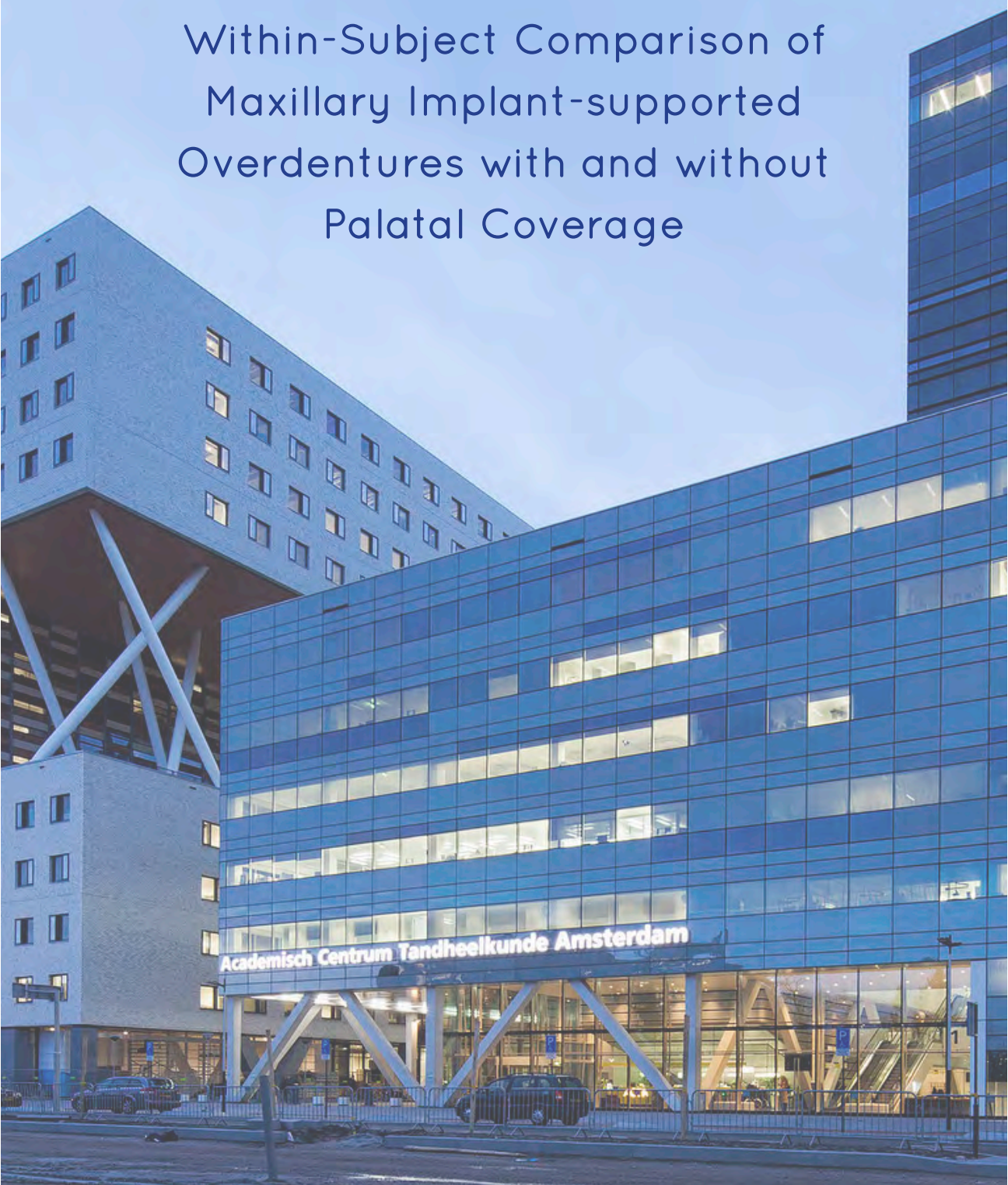
4

Within-Subject Comparison of Maxillary Implant-supported Overdentures with and without Palatal Coverage



Within-Subject Comparison of Maxillary Implant-Supported Overdentures with and without Palatal Coverage

Anja Zembic, Dr.;* Ali Tahmaseb, Dr. PhD;† Daniel Wismeijer, Prof. Dr.‡

ABSTRACT

Purpose: The purpose of this study was to compare patient-reported outcomes for maxillary implant-supported overdentures with and without palatal coverage.

Materials and Methods: Twenty-one maxillary edentulous patients (six women, 15 men) were included. In total, 42 implants were inserted in the anterior maxilla. All patients received implant-supported overdentures on two retentive anchors with palatal coverage for 2 months. Thereafter, patient satisfaction was assessed by means of questionnaires capturing the oral health impact profile (OHIP) on functional limitation, physical pain, psychological discomfort, physical, psychological and social disability, and handicap. Additionally, cleaning ability, general satisfaction, speech, comfort, esthetics, stability, and chewing ability were rated. Subsequently, palatal coverage was reduced, and the patients wore the overdentures for another 2 months. Patient satisfaction was obtained in the same way as above, and the evaluated parameters were compared for the two overdenture designs.

Results: There were no significant differences between implant-supported overdentures with and without palatal coverage for any of the OHIP domains. The evaluation of additional parameters revealed significantly higher patient satisfaction for esthetics (mean difference 8.8 mm ± 24.6) and taste (mean difference 28.4 mm ± 29.9) without palatal coverage, $p < .01$.

Conclusions: Within the limits of this study, maxillary overdentures supported by two implants were equally satisfactory with and without palatal coverage.

KEY WORDS: clinical trial, complete, dental implants, dental prosthesis, denture, edentulous, implant-supported, jaw, maxilla, palate, patient satisfaction, quality of life, upper

INTRODUCTION

Today, implant-supported overdentures represent a reliable treatment option for both mandible and maxilla.[1–7] However, several systematic reviews and studies concluded that there is a lack of scientific evidence for implant-supported overdentures in the upper jaw with regard to patient satisfaction; implant survival rates; and biological, technical, and prosthetic outcomes.[8–11] Thus, more clinical research is needed, including patient satisfaction on implant-supported maxillary overdentures, both with splinted and unsplinted dental implants.

In order to achieve a satisfying result with a conventional maxillary overdenture, the overdenture design relies on good support and anatomy of the hard palate, together with good adaptation and vestibular seal at the

*Assistant professor, Division of Fixed Prosthodontics, School of Dental Medicine, University of Bern, Bern, Switzerland; PhD student, Department of Oral Implantology and Prosthetic Dentistry, Academic Center for Dentistry Amsterdam (ACTA), Move Research Institute, Amsterdam, The Netherlands; †associate professor, Department of Oral Implantology and Prosthetic Dentistry, Academic Center for Dentistry Amsterdam (ACTA), Move Research Institute, Amsterdam, The Netherlands, ‡professor, Department of Oral Implantology and Prosthetic Dentistry, Academic Center for Dentistry Amsterdam (ACTA), Move Research Institute, Amsterdam, The Netherlands

Reprint requests: Dr. Anja Zembic, Department of Oral Implantology and Prosthetic Dentistry, Academic Centre for Dentistry Amsterdam (ACTA), Gustav Mahlerlaan 3004, 1081 LA Amsterdam, The Netherlands; e-mail: a.zembic@acta.nl

DOI 10.1111/cid.12125

borders.[12–14] It has been demonstrated that the tuberosity coverage by the denture is more important for retention than the coverage of the palate.[15] Reduction of the palatal coverage offers several benefits for the patients, including an enhanced taste sensation, better control of the gag reflex, a positive effect on salivary flow rate, and even phonetic benefits.[14,16–19] However, reduction of the palatal coverage might negatively influence the overdenture retention.

A former study evaluated the effects on retention by reducing the palatal coverage of complete maxillary overdentures.[20] The results suggested that the ability to withstand tilting loads was insignificantly altered by reduction of the palatal coverage. In addition, patient responses to interviews indicated that retention also remained unchanged while eating.[20] A further study failed to show significant differences in the effect of palatal coverage in complete overdentures.[21]

Thus, based on these findings, patients seem to be satisfied with conventional overdentures even without palatal coverage, which might function as effectively as the conventional overdenture design.[20,21]

Given that the retention of conventional overdentures is influenced to a greater extent by tuberosity coverage of the overdenture, one might expect that the removal of the palatal coverage in implant-supported overdentures would not impair denture retention significantly.[15] As a result, the need for palatal coverage in implant-supported maxillary overdentures may be questioned.

So far, no significant differences were observed in one study evaluating patient satisfaction for implant overdentures with and without palatal coverage.[2] In that study, four implants were placed, and the overdenture was supported by a bar.[2] There are no scientific data available on the influence of implant support for overdentures with a reduced palatal coverage. The question whether or not there is a difference in patient satisfaction for overdentures with or without palatal coverage supported by a reduced number of implants can therefore not be answered so far.

The hypothesis of the present study was that patient satisfaction is higher for maxillary overdentures supported by two implants without palatal coverage compared to overdentures with palatal coverage.

The aim of the present prospective crossover study was to test whether or not there is a difference in patient-reported outcomes for maxillary overdentures supported by two implants with and without palatal coverage.

MATERIALS AND METHODS

Study Design and Patients

The present study was a within-subject prospective clinical case series. The study protocol and procedures were approved by the local ethical committee (Medisch Ethische Toetsingscommissie van Vrije Universiteit Medisch Centrum). All patients were informed about the study aim and procedure and gave their written informed consent. Details of the study design and the surgical and prosthetic procedures were reported in a previous publication.[22] In brief, 21 patients experiencing problems with their existing conventional dentures were included in the present study.

Surgery and Prosthodontics

First, the existing overdentures were either adjusted in terms of rebasing or relining, or new overdentures were made according to proven standards for overdentures.[23] Thus, it was assured that all patients had conventional overdentures fulfilling functional and esthetic criteria. Thereafter, a cone beam computed tomography scan (NewTom 5G, QR, Verona, Italy) was performed for implant planning. Subsequently, two reduced-diameter implants (Roxolid®, 3.3 mm diameter, Institut Straumann AG, Basel, Switzerland) were placed in the anterior maxilla, preferably in the canine area and by means of guided surgery (coDiagnostiX, Dental Wings GmbH, Freiburg, Germany). In case of minor bone defects, local guided bone regeneration (GBR) was applied. In this case, the healing pattern was submerged for 4 months, whereas in all other cases, the healing pattern was transmucosal for 2 months. An impression was taken after the healing period and 1 week after abutment connection for implants with GBR using the overdentures as individual tray. Access holes were prepared for that purpose in the implant area. The overdentures were sent to the lab for conversion to implant-supported overdentures with an incorporated metal frame. The patients wore provisional overdentures during this time, which were duplicates of the conventional overdentures.

Implant-supported upper overdentures were inserted approximately 3 and 5 months after implant placement, depending on the healing pattern. The overdentures were supported by two titanium retentive anchors, which were screwed onto the implants with a defined torque of 35 Ncm (Retentive anchor abutment, Institut Straumann AG). The titanium matrices were

already polymerized into the base of the overdentures by the dental technician (Titanium matrix for retentive anchor, Institut Straumann AG). Patient instructions were given concerning handling of the overdentures and oral hygiene specifically for implant overdentures. The occlusion was controlled and corrected in order to be balanced, lingualized, and without anterior contacts in habitual occlusion.[24–26]

Patient-Reported Outcomes

All participants measured their satisfaction and perception of the overdentures by responding to questionnaires using visual analogue scales (VAS).[3] The VAS consisted of a 100 mm horizontal line, which was confined at both ends with the below cited anchor words. The patients were asked to draw a vertical line anywhere across the horizontal line, where their perception was best represented. Patient satisfaction was assessed 2 months after insertion of the implant-supported overdentures. The time period of 2 months was previously defined as an adequate time period for patients to adapt and rate new overdentures.[3]

The oral health impact profile (OHIP) for edentulous patients was used to measure patient satisfaction on functional limitation; physical pain; psychological discomfort; physical, psychological, and social disability; and handicap (OHIP-20E). The OHIP questionnaire was in Dutch. The anchor words were "none" (at 0 mm) and "severe" (at 100 mm). Higher scores implied poorer patient satisfaction.

In addition, the questionnaire involved the evaluation of cleaning ability, general satisfaction, speech, comfort, esthetics, stability, chewing ability, function, and taste. The anchor terms for evaluation were "completely satisfied" and "completely dissatisfied." Higher scores meant higher patient satisfaction, with the exception of the evaluation of speech, where higher scores implied decreased patient satisfaction.

At the 8-week follow-up, maxillary overdentures were sent to the lab, and the palatal coverage was reduced by the dental technician as close as possible to the metal frame (Figures 1–3). Thus, the reduction of the palatal coverage was performed in a nonstandardized way, dependent on the dimensions of the metal frame. The patients wore the implant-supported maxillary overdentures without palatal coverage for another 2 months. At the 2-month follow-up, they filled in the questionnaires again (see above). The occlusion was regularly checked. The patients could thereafter choose which overdenture design they would like to keep (i.e., either with or without palatal coverage). In cases where the patients preferred a closed palate, the overdentures were sent to the lab for closure of the palate with denture acrylic.

Figure 1 Implant-supported maxillary overdenture with marking for the technician where to shorten the palatal coverage.

Statistical Analysis

Standard statistics was applied calculating means and standard deviations of patient-reported outcomes for implant-supported overdentures with and without

Figure 2 Implant-supported maxillary overdenture with reduced palatal coverage, metal frame, and titanium matrices (basal view).

Figure 3 Implant-supported maxillary overdenture with reduced palatal coverage (occlusal view).

palatal coverage. The analysis was performed by means of a statistical software program (SAS® Version 9.2, SAS Institute Inc., Cary, NC, USA).

Before and after treatment measurements were analyzed with the Wilcoxon matched pairs signed rank test (proc univariate). To detect the differences between overdentures with and without palatal coverage, the Wilcoxon Mann-Whitney *U* test was applied (proc npar1way). For evaluation of the chewing ability, average values of different subgroups were calculated (chewing ability for different types of food). The level of statistical significance was set at 5%.

RESULTS

Patients

Twenty-one patients (six women, 15 men) with a mean age of 63 years (range 52–81 years) were treated in the present study. Twelve patients (four women, eight men) were provided with a new pair of conventional overdentures. In the remaining nine patients (two women, seven men), adjustments were made to the existing overdentures by means of relining or rebasing. The patients received in total 42 diameter-reduced implants (Tissue Level Roxolid®, 3.3 mm diameter, Institut Straumann AG, Basel, Switzerland) in the anterior maxilla. A flapless procedure was performed for 36 implants, whereas six implants were placed with simultaneous minor GBR and an open flap procedure. All patients were supplied with maxillary overdentures supported by two retentive anchors (Retentive anchor abutment, Institut Straumann AG). Implants placed without GBR were loaded at 3 months, whereas implants placed with GBR were loaded at 5 months.

The opposing dentitions comprised of mandibular implant-supported overdentures in 17 patients (15 patients with two implants and a bar, one patient with three implants and a bar, and one patient with two implants and retentive anchors), conventional mandibular overdentures in three patients, and three remaining natural teeth and a frame denture in one patient.

Patient-Reported Outcomes

The mean values of the OHIP domains (in mm) with standard deviations are presented in Table 1 for implant-supported overdentures with (IPp) and without palatal coverage (IPw).

There were no significant differences between the two overdenture designs for any of the OHIP domains (Table 2). Both prosthetic designs were rated highly (i.e., low VAS ratings) with mean VAS ratings for OHIP subgroups ranging from 5.3 to 19.0 mm (Table 1).

TABLE 1 Mean Values and Standard Deviations of All OHIP Subgroups for Implant-Supported Dentures with Palatal Coverage and without Palatal Coverage. Higher Scores Imply Poorer Patient Satisfaction

OHIP Subgroups	IPp Mean	IPp SD	IPw Mean	IPw SD
Functional limitation	19.0	16.2	16.5	19.6
Physical pain	12.9	15.4	9.7	13.6
Psychological discomfort	15.5	18.1	7.9	13.7
Physical disability	14.3	17.6	13.1	21.3
Psychological disability	12.9	19.7	7.6	12.1
Social disability	6.8	12.8	5.3	7.9
Handicap	10.2	14.1	7.5	13.4

OHIP, oral health impact profile; IPp, implant-supported dentures with palatal coverage; IPw, implant-supported dentures without palatal coverage.

TABLE 2 Differences in VAS Values for OHIP Subgroups (Mean Values and Standard Deviations) for Implant-Supported Dentures with Palatal Coverage and without Palatal Coverage. Wilcoxon Matched Pairs Signed Rank Test Was Applied (the Level of Significance Was Set at 5%)

OHIP Subgroups	Mean Difference IPp to IPw	SD of Difference IPp to IPw	Median Difference IPp to IPw	*p* Value	*n*
Functional limitation	−3.7	24.1	−6.1	n.s.	17
Physical pain	−4.4	20.9	−2.3	n.s.	18
Psychological discomfort	−4.5	17.0	−0.5	n.s.	18
Physical disability	−1.2	27.4	−1.8	n.s.	18
Psychological disability	−4.6	24.1	−0.1	n.s.	18
Social disability	−1.5	15.0	0	n.s.	18
Handicap	−3.2	11.6	0	n.s.	18

VAS, visual analogue scales; OHIP, oral health impact profile; IPp, implant-supported dentures with palatal coverage; IPw, implant-supported dentures without palatal coverage; n.s., not significant.

The greatest satisfaction (lowest rating) was found for social disability both for implant-supported maxillary overdentures with and without palatal coverage (OHIP IPp 6.8 ± 12.8 mm; IPw 5.3 ± 7.9 mm). The satisfaction was least (highest rating) for functional limitation both for IPp and IPw (OHIP IPp 19.0 ± 16.2 mm; IPw 16.5 ± 19.6 mm).

The evaluation of the VAS scores with concern to general variables (cleaning ability, general satisfaction, ability to speak, comfort, esthetics, stability, chewing ability, function, and taste) revealed significantly higher patient satisfaction for esthetics (mean difference 8.8 ± 24.7 mm) and taste (mean difference 28.4 ± 29.9 mm) with IPw (higher scores) compared with IPp, $p < .01$ (Tables 3 and 4). There was also a high patient satisfaction for the judgment of general variables with mean VAS scores ranging from 58.5 to 88.6 mm (Table 3).

The highest patient satisfaction was evident for esthetics with IPw (mean 88.6 ± 14.9 mm), whereas the patients were least satisfied with concern to taste with IPp (mean 58.5 ± 23.3 mm). Stability for IPp was judged with a mean score of 69.4 mm ± 35.2 mm and for IPw with a mean score of 77.7 ± 25.2 mm. All remaining parameters both for IPp and IPw were judged with scores of 70 mm or more, representing a high patient satisfaction. At the end of the evaluation phase (4 months postinsertion of implant dentures), 16 patients chose an open palate, whereas five patients asked for palatal closure.

DISCUSSION

The present study demonstrated that patient satisfaction does not differ significantly for implant-supported overdentures with or without palatal coverage except for a more positive assumption for esthetics and taste.

TABLE 3 Patient Satisfaction (Mean Values and Standard Deviations) for General Variables of Implant-Supported Dentures with and without Palatal Coverage. Higher Scores Imply Higher Patient Satisfaction

Variables	IPp Mean	IPp SD	IPw Mean	IPw SD
Cleaning ability	86.5	13.9	86.7	16.8
General satisfaction	84.6	21.6	87.8	16.1
Ability to speak	25.9	33.2	31.1	35.9
Comfort	71.6	34.6	71.9	35.0
Esthetics	79.6	28.7	88.6	14.9
Stability	69.4	35.2	77.7	25.2
Chewing ability	74.6	19.8	80.0	22.0
Function	76.6	24.8	84.6	23.8
Taste	58.5	23.3	86.2	10.3

IPp, implant-supported dentures with palatal coverage; IPw, implant-supported dentures without palatal coverage.

TABLE 4 Differences in VAS Values for General Variables (Mean Values and Standard Deviations) for Implant-Supported Dentures with Palatal Coverage and without Palatal Coverage. Wilcoxon Matched Pairs Signed Rank Test Was Applied (the Level of Significance Was Set at 5%)

Variables	Mean Difference IPp to IPw	SD of Difference IPp to IPw	Median Difference IPp to IPw	*p* Value	*n*
Cleaning ability	2.6	18.1	3.1	n.s.	16
General satisfaction	5.7	26.7	0	n.s.	16
Ability to speak	2.9	43.1	2.6	n.s.	16
Comfort	1.0	39.5	4.1	n.s.	16
Esthetics	8.8	24.7	2.0	<0.01	16
Stability	6.2	42.3	0	n.s.	15
Chewing ability	7.2	24.7	4.3	n.s.	16
Function	7.1	25.4	6.8	n.s.	17
Taste	28.4	29.9	21.0	<0.01	15

VAS, visual analogue scales; IPp, implant-supported dentures with palatal coverage; IPw, implant-supported dentures without palatal coverage; n.s., not significant.

Thus, the hypothesis that patient-reported outcomes are significantly better for maxillary overdentures supported by two implants without palatal coverage could only be partly substantiated.

General Satisfaction

To date, there is no scientific evidence with regard to the optimum number of implants to be placed when treating the edentulous maxilla.[27–29] In the present study, a minimally invasive treatment was chosen with the placement of two anterior implants. The high general patient satisfaction in the present study is in accordance with the results of a systematic review, where the use of two implants in the maxilla did not compromise patient satisfaction.[30] Another study evaluating patient satisfaction with implant-supported overdentures found a high general patient satisfaction independent of the number of implants per denture or attachment type (splinted vs nonsplinted implants).[31] Despite speculations that implant survival or patient satisfaction may not be compromised with the use of two implants to support maxillary overdentures, this treatment option is still not supported by the literature today.[32,33]

The patients in the present study completed questionnaires after wearing overdentures with and without palatal coverage for a time period of 2 months each. Two months was considered to be an adequate period for patients to adapt to new overdentures and to give stable responses to questionnaires.[3] The present findings showed no significant deterioration of functional limitation or stability when the palatal overdenture coverage was reduced. These results are consistent with OHIP outcomes of similar studies on three to four maxillary implants supporting overdentures with and without palatal coverage.[2,34]

Regarding the effectiveness of palatal coverage in complete overdentures, a study found that eight out of 10 patients were more comfortable with reduced palatal coverage than with complete palatal coverage.[21] All the selected patients had a favorable residual ridge height. Considering these favorable conditions, the authors concluded that conventional overdentures with reduced palatal coverage could be as effective as overdentures with complete palatal coverage.[21]

Several clinical studies have evaluated the effect of palatal coverage at maxillary implant-supported overdentures.[2,34–38] In all studies, the overdentures were supported by a higher number of implants than in the present study.[2,34–38] Only two of these studies used an unsplinted attachment system like in the present study.[34,35] Three studies were of the same design as the present one and compared the effect of the palatal coverage in the same patient group (within-subject comparison).[2,34,37]

The most recent study evaluated three maxillary implants, which were splinted in 20 patients and unsplinted in another 20 patients.[34] Following 1 year of function with full palatal coverage, the palatal coverage was shortened and patient satisfaction was analyzed by means of OHIP questionnaires after another year of function. There was no significant difference with regard

to the prosthetic design (full or reduced palatal coverage, splinted or unsplinted implants). Most patients (85%) preferred dentures with reduced palatal coverage and did not report impaired retention.[34]

In a study on four maxillary-splinted implants, no significant differences with respect to general satisfaction, stability, retention, comfort, esthetics, and cleaning ability were observed for overdentures with and without palatal coverage.[2] According to the results of a clinical trial on speech with maxillary implant overdentures, no significant differences were found between overdentures supported by four implants with or without palatal coverage.[37]

On the basis of these results, including those from the current study, reduced palatal coverage of maxillary implant-supported overdentures seems to be satisfactory for patients and independent of the number of inserted implants.

Esthetics

The finding that esthetics was significantly higher for overdentures without palatal coverage is difficult to explain as the overdentures did not change with concern to their outward appearance despite the removal of the palatal coverage. Reducing the palatal coverage reduced the palatal bulk and might have given the patients a more natural feeling, which in turn might have positively affected their perception of esthetics. A "more natural" feeling for overdentures without palatal coverage was in fact described in two patients in a previous within-subject comparison even though no significant differences for esthetics were detected between implant-supported overdentures with and without palatal coverage.[2]

Taste

Taste and ability to chew were listed to be among the most frequently reported criteria for success in implant dentistry at patient satisfaction level in a systematic review.[39] This was documented in the present study demonstrating a significantly improved taste sensation for overdentures without palatal coverage. These data are in accordance with several studies on conventional and implant-supported overdentures.[14,20,21,34] The appreciation of taste is a complex sequence of sensory and motor events including mastication, manipulation of the bolus, and deglutition.[40] The tactile sensation is thereby crucial for the taste when the tongue with its taste buds is pressed against the palate, which is hindered in case of complete palatal coverage.

Functional Limitation

Functional limitation represents the difficulty of chewing food among other factors influencing the function.[41] The patients in the present study were not much hampered when using overdentures with palatal coverage (mean OHIP score 19.0 ± 16.2 mm) and without palatal coverage (mean OHIP score 16.5 ± 19.6 mm). A study on maxillary overdentures supported by three implants reported slightly better scores for functional limitation both for dentures with (mean OHIP score 13.4 ± 2.6) and without palatal coverage (mean OHIP score 13.9 ± 3.1).[34] Likewise in the present study, functional limitation did not differ significantly for dentures with and without palatal coverage.[34]

Stability and Retention

In a recent review on implant overdentures, it was stated that the stability of the overdenture is enhanced when the implants are placed in the anterior maxilla.[32] Eliminating the palatal coverage of complete overdentures did not affect negatively the stability.[21] Thereby, occlusion is decisive and was thought to even enhance stability of a palateless maxillary overdenture when being well balanced and noninterfering.[42] The present results corroborate these findings with stability not compromised by the reduction of the palatal coverage. The anterior placement of the implants as well as the balanced occlusion might have added stability.

Aside from this finding, it was suggested to make a complete palatal coverage for maxillary overdentures supported by two implants in order to achieve adequate stability and retention.[43] In complete maxillary overdentures, reduction of the palatal coverage was shown to weaken the retentive potential.[20,21,44]

Different important factors are involved in overdenture retention, such as muscular retentive forces, forces associated with the attachment system, saliva amount and viscosity, overdenture supporting area, direction of insertion, and implant angulation.[44,45] In addition, neuromuscular reflexes develop and are conditioned by the overdenture outline, which enable the patient to tolerate newly designed overdentures after some time.[44] In the present study, all patients experienced problems with their conventional overdentures prior to inclusion to the study. It is plausible that the

insertion of two implants improved overdenture retention independent of the extent of palatal coverage.

The evaluation of patient satisfaction is a decisive instrument to measure the effectiveness and success of a treatment.[46,47] However, less than 2% of studies on implant overdentures cover patient-reported outcomes.[41] According to the outcomes of the ITI consensus conference in 2008, there is a need for clinical trials to scientifically and clinically validate the use of freestanding implants supporting overdentures with or without palatal coverage.[9] The present study may offer a satisfactory, reasonably priced individual, patient-oriented treatment option.[1,6] One limitation is the rather small number of patients, even though it is higher than in other studies on two maxillary implants.[48–50] The use of a within-subject study design offered several advantages. In this way, each subject served as its own control, which reduced error in variation associated with individual differences. The reduced variability in turn increased the power of the study.

CONCLUSIONS

On the basis of these short-term results, patient satisfaction was favorable and similar for both implant-supported maxillary overdentures with and without palatal coverage. The majority of the patients preferred reduced palatal coverage.

ACKNOWLEDGMENTS

This study was funded by the Academic Center for Dentistry Amsterdam (ACTA), the Netherlands. Study materials were provided free of charge by Institut Straumann AG, Basel, Switzerland. Thanks go to Dr. Walter Bürgin, School of Dental Medicine, University of Bern, Switzerland for the statistical analysis and to Sirarpi Pogosian, Academic Center for Dentistry Amsterdam (ACTA), the Netherlands for the collection of patient data. Further gratitude goes to Martin Bub and his team from the technical laboratory Zutphen (Zutphen, the Netherlands) for their commitment in fabrication and adjustment of the overdentures.

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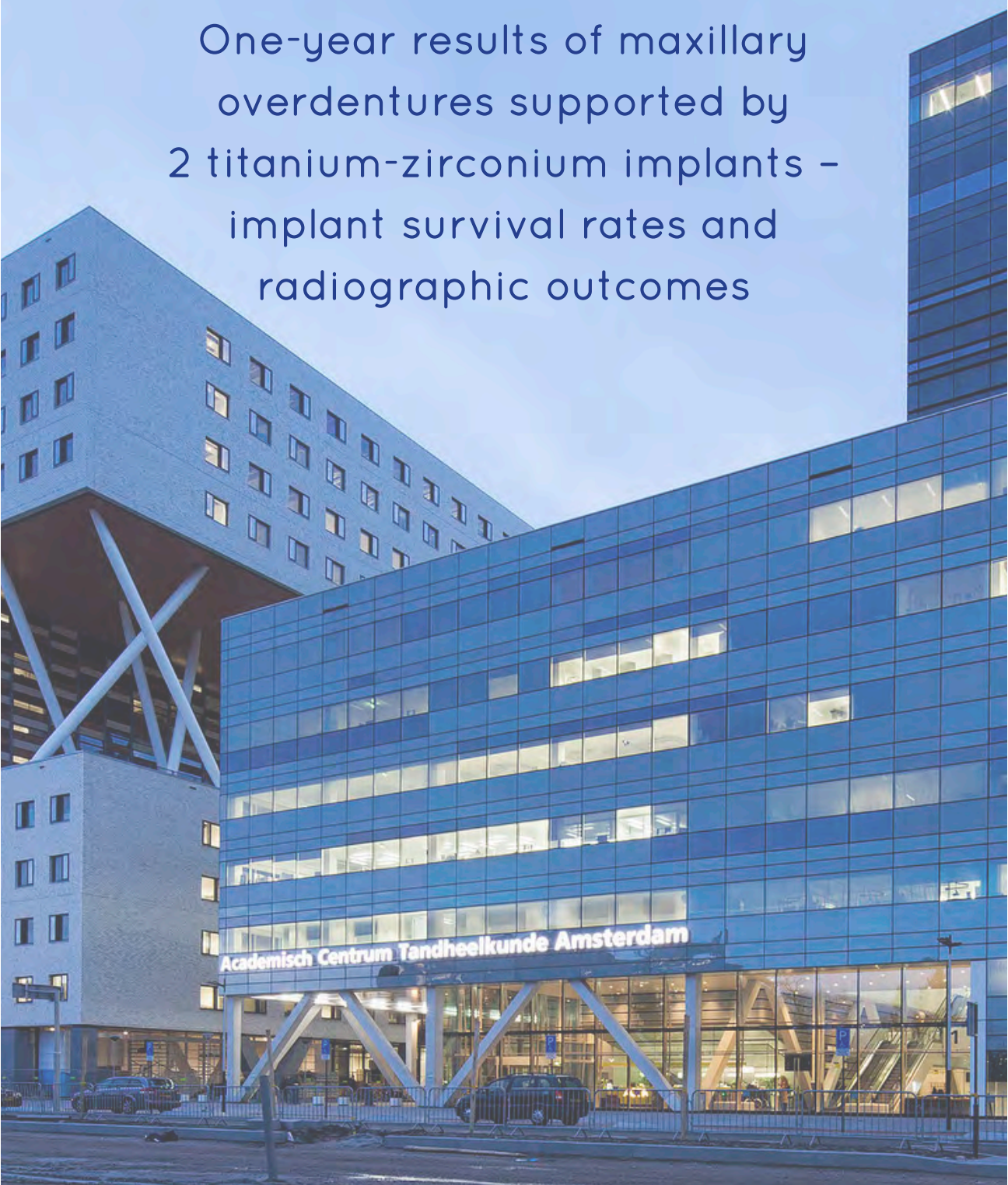
One-year results of maxillary overdentures supported by 2 titanium-zirconium implants – implant survival rates and radiographic outcomes



CLINICAL ORAL IMPLANTS RESEARCH

Anja Zembic
Ali Tahmaseb
Ronald E. Jung
Daniel Wismeijer

One-year results of maxillary overdentures supported by 2 titanium–zirconium implants – implant survival rates and radiographic outcomes

Authors' affiliations:
Anja Zembic, Department of Oral Implantology and Prosthetic Dentistry, Academic Center for Dentistry Amsterdam (ACTA), Move Research Institute, Amsterdam, The Netherlands
Clinic of Fixed and Removable Prosthodontics and Dental Material Science, University of Zurich, Zurich, Switzerland
Ali Tahmaseb, Department of Oral Implantology and Prosthetic Dentistry, Academic Center for Dentistry Amsterdam (ACTA), Move Research Institute, Amsterdam, The Netherlands
Ronald E. Jung, Clinic of Fixed and Removable Prosthodontics and Dental Material Science, University of Zurich, Zurich, Switzerland
Daniel Wismeijer, Department of Oral Implantology and Prosthetic Dentistry, Academic Center for Dentistry Amsterdam (ACTA), Move Research Institute, Amsterdam, The Netherlands

Corresponding author:
Dr. Anja Zembic, DMD
Clinic of Fixed and Removable Prosthodontics and Dental Material Science, University of Zurich, Plattenstrasse 11, 8032 Zurich, Switzerland
Tel.: +41 44 634 32 60
Fax: +41 44 634 43 05
e-mail: anja.zembic@zzm.uzh.ch

Key words: alveolar bone loss, ball anchor, bone resorption, dental implants, dental prosthesis, edentulous, implant-supported, jaw, maxilla, survival rate, titanium–zirconium

Abstract

Objective: To assess implant survival rates and peri-implant bone loss of 2 titanium–zirconium implants supporting maxillary overdentures at 1 year of loading.

Material and Methods: Twenty maxillary edentulous patients (5 women and 15 men) being dissatisfied with their complete dentures were included. In total, 40 diameter-reduced titanium–zirconium implants were placed in the anterior maxilla. Local guided bone regeneration (GBR) was allowed if the treatment did not compromise implant stability. Following 3 to 5 months of healing, implant-supported overdentures were inserted on two ball anchors. Implants and overdentures were assessed at 1, 2, 4, and 8 weeks after implant insertion and 2, 4, and 12 months after insertion of overdentures (baseline). Standardized radiographs were taken at implant loading and 1 year. Implant survival rates and bone loss were the primary outcomes.

Results: Nineteen patients (1 dropout) with 38 implants were evaluated at a mean follow-up of 1.1 years (range 1.0–1.7 years). One implant failed resulting in an implant survival rate of 97.3%. There was a significant peri-implant bone loss of the implants at 1 year of function (mean, 0.7 mm, SD = 1.1 mm; median: 0.48 mm, IQR = 0.56 mm).

Conclusions: There was a high 1-year implant survival rate for edentulous patients receiving 2 maxillary implants and ball anchors as overdenture support. However, several implants exhibited an increased amount of bone loss of more than 2 mm. Overdentures supported by 2 maxillary implants should thus be used with caution as minimally invasive treatment for specific patients encountering problems with their upper dentures until more long-term data is available.

In the past, complete dentures were the only treatment option for edentulous patients. Demographic trends indicate that the number of edentulous patients will be relatively high in future; thus, the need for complete dentures might persist (Carlsson & Omar 2010; Polzer et al. 2010).

Dental implants provided the edentulous patients with new treatment alternatives and several factors, such as patient satisfaction, denture retention, function, and quality of life improved significantly (Bouma et al. 1997; Wismeijer et al. 1997; Strassburger et al. 2006; Zembic & Wismeijer 2014).

Even though the frequency of placing oral implants is increasing, a previous review reported differing and small numbers (0.3%–11%) of edentulous patients undergoing an implant treatment (Zitzmann et al. 2007). The most common reason for the patients not to choose for implants was found to be anxiety for surgical risks, followed by costs (Walton & MacEntee 2005; Ellis et al. 2011).

Usually maxillary dentures show less retention problems than mandibular dentures. This is mainly caused by an enhanced vacuum effect through the anatomic shape of the maxilla. Once patients start to complain on their maxillary dentures, the retention is often compromised due to advanced ridge resorption. In these situations, bone augmentation techniques such as guided bone regeneration (GBR) or autogenous bone grafts are often inevitable when considering an implant treatment (Chiapasco et al. 2009). This in turn increases the risk for the patient, the patient's morbidity, the costs, and the treatment time (Sennerby & Roos 1998; Stellingsma et al. 2004). Hence, the aversion toward implants becomes evident.

Date:
Accepted 11 April 2016

To cite this article:
Zembic A, Tahmaseb A, Jung RE, Wismeijer D. One-year results of maxillary overdentures supported by 2 titanium–zirconium implants – implant survival rates and radiographic outcomes.
Clin. Oral Impl. Res. **00**, 2016,000–000.
doi: 10.1111/clr.12863

One possibility to avoid bone-grafting procedures might be the use of narrow-diameter implants in the anterior maxilla. Therefore, patient's risks and discomforts are reduced in situations with limited bone quantity. The survival of narrow-diameter implants was found to be similar to regular-diameter implants (Sohrabi et al. 2012). Despite respectable survival rates, it was advised to use narrow-diameter titanium implants with caution due to risk of fracture in clinical use (Buser & von Arx 2000; Allum et al. 2008).

A recently introduced diameter-reduced implant out of titanium and zirconium alloy offers superior mechanical strength compared with grade 4 titanium and might help overcome the risk of fracture (Ho et al. 2008). In addition, preclinical and clinical studies reported similar osseointegration of this implant to titanium implants (Thoma et al. 2011; Al-Nawas et al. 2012; Barter et al. 2012; Chiapasco et al. 2012; Gottlow et al. 2012).

A systematic review addressed the question of how many implants are ideal as overdenture support (Roccuzzo et al. 2012). The authors concluded that no answer could be given with regard to the maxilla on the basis of the current evidence. Former systematic reviews with the same goal advised to place at least 4 to even 6 implants in the maxilla (Sadowsky 2007; Klemetti 2008; Gallucci et al. 2009; Slot et al. 2010). This relatively high number of implants as overdenture support makes the treatment both invasive and costly. More minimal-invasive treatment options should be offered to edentulous patients with denture problems out of the above-mentioned reasons. It remains unclear however, how many implants can be minimally inserted in the edentulous maxilla as overdenture support (Jemt et al. 1996; Kronstrom et al. 2006; Klemetti 2008; Roccuzzo et al. 2012).

The placement of 2 implants in the maxilla, as support for overdentures, was a treatment option that did not prevail in the past due to low implant survival rates and pronounced bone loss (Quirynen et al. 1991; Bergendal & Engquist 1998; Sanna et al. 2009). The implants used in these studies had a machined surface. The implant surface is crucial for implant osseointegration. Hence, rough-surface implants replaced machined-surface implants due to their superior effect on bone integration (Han et al. 1998; Ivanoff et al. 2001; Rasmusson et al. 2001; Wennerberg & Albrektsson 2009). Consequently, the survival rates significantly increased for rough-surface implants placed in the edentulous maxilla compared with machined-surface implants at 1, 3, 5, and 10 years (Lambert et al. 2009).

The new titanium–zirconium implant exhibits the successful highly hydrophilic, sandblasted, large-grit, acid-etched surface. Based on the encouraging clinical results, this implant might allow new treatment possibilities, such as the formerly unestablished but minimal-invasive treatment with 2 implants to support maxillary overdentures (Mericske-Stern et al. 2000).

The aim of this prospective clinical study was to assess survival rates and peri-implant bone loss of 2 titanium–zirconium implants supporting maxillary overdentures at 1 year of loading.

Material and methods

Patients and study procedure

This study was designed as a prospective clinical cohort study including 20 edentulous patients experiencing problems with their maxillary complete dentures.

These patients were part of a previously published study describing the details of the procedures (Zembic & Wismeijer 2014).

In brief, the study was approved by the local ethical committee (Medisch Ethische Toetsingscommissie van Vrije Universiteit Medisch Centrum). The treatment was performed at the Academic Center for Dentistry Amsterdam (ACTA), the Netherlands. All patients were treated by one clinician.

Implant planning

Upon adjusting the existing dentures or fabricating new ones, a cone-beam computed tomography (CBCT) scan (NewTom 5G, QR, Verona, Italy) was performed using a scan template (duplicate of the denture with barium sulfate). Implants were planned in the prosthetic canine position preferably (coDiagnostiX, Dental Wings Inc. Montreal, Canada). In case of major insufficiency of bone quantity in this region (primary bone graft inevitable), implants were planned posterior or anterior to the canine. In case of minor insufficiency of bone quantity (dehiscence or fenestration defects) not compromising implant stability, implants were planned in canine area.

The automatic parallelization feature of the planning software was used to ensure the most parallel position of the 2 implants in the mesio-distal as well as bucco-lingual plane. When needed, the parallelized implant position was adjusted manually according to the individual bone conditions. The scan template was translated into a template for guided surgery according to the virtual implant planning and using the manufacturer's device (gonyX™, Institut Straumann AG, Basel, Switzerland).

Surgery

The patients received antibiotics as single shot dose 1 preoperative (Amoxicillin 3 g) (Amoxicillin Sandoz® Pharmaceuticals AG, Rotkreuz, Switzerland). Mouth rinsing was administered 1 day before surgery with a solution of 0.12% chlorhexidine digluconate (Perio·Aid®, Dentaid, Barcelona, Spain).

In situations with no bone defects according to the virtual planning, soft tissue punches were performed through the sleeves by means of disposable biopsy tissue punches with a standardized diameter of 4 mm (Integra™ Miltex®, Plainsboro, New Jersey, USA). Subsequently, guided drilling was performed (Straumann Guided® Surgery kit, Institut Straumann AG, Basel, Switzerland). Two diameter-reduced implants (Roxolid® Tissue Level, 3.3 mm diameter, Regular Neck, Institut Straumann AG, Basel, Switzerland) were placed through the guided implant mount. Implants with a standard shoulder height of 2.8 mm or with a reduced shoulder height of 1.8 mm were placed, dependent on the mucosa thickness. The rough–smooth border of the implants was placed at either bone crest or slightly subcrestal by means of a guided vertical reference. Closure screws or healing abutments were inserted dependent on the mucosa thickness, and the implants were exposed to transmucosal healing for 2 months.

In situations with expected bone defects, a flap was raised and guided bone regeneration (GBR) was applied simultaneously with the placement of two diameter-reduced implants. Implants were placed in the same way as mentioned above. Autogenous bone chips gained from the surrounding bone were applied on the exposed implant threads, followed by a xenograft material (Bio-Oss®, Geistlich Pharma AG, Wolhusen, Switzerland). A resorbable collagen membrane was used to cover the graft (Bio-Gide®, Geistlich Pharma AG, Wolhusen, Switzerland). Closure screws were inserted into the implants. A periosteal releasing incision was performed if needed and the flap was closed tension-free with non-resorbable PTFE monofilament sutures (Cytoplast™, Osteogenics Biomedical, Inc., Lubbock, USA). Submucosal implant healing was allowed for 4 months.

The patients were instructed postoperatively to rinse twice daily for 2 weeks with a

solution of 0.12% chlorhexidine digluconate (Perio·Aid®, Dentaid, Barcelona, Spain).

Analgesics (Brufen® Bruis 600 mg, Abbott, Illinois, USA) were prescribed according to patient's individual requirements. All patients were instructed not to wear the maxillary dentures for 1 week after implant surgery. One week postoperatively, sutures were removed and the dentures were thoroughly grinded out in the implant area. Soft relining was carried out occasionally (Soft-Liner, GC Corporation, Tokyo, Japan). If the implant healing was submerged, abutment connection was performed after 4 months and healing abutments were inserted. One week thereafter, implant impressions were made. In case of transmucosal healing, implant impressions were performed 2 months after implant insertion. Radiographs of the implants were performed using the long-cone parallel technique for control of the correct fit of the impression posts (Updegrave 1951).

Prosthodontic procedure

Definitive overdentures were inserted 3 and 5 months after implant placement. Thus, all implants were loaded conventionally (Esposito et al. 2007).

At the day of overdenture insertion, 2 titanium retentive anchors with a standardized height of 3.4 mm (Retentive anchor abutment, Institut Straumann AG) were screwed into the implants with a defined torque of 35 Ncm. The corresponding matrices (Titanium matrix for retentive anchor, Institut Straumann AG, Switzerland) were incorporated into the overdentures by the dental technician. The overdentures were designed with a metal framework and conventional full palatal coverage. The patients wore these overdentures for 2 months. Subsequently, the overdentures were sent to the laboratory for reduction of the palatal coverage and the patients wore the modified overdentures for another 2 months. This overdenture modification was part of another research project (Zembic et al. 2015). The patients could thereafter choose which overdenture type they preferred, with either closed or open palatal design.

The occlusion of the overdentures was controlled and corrected to be balanced and without anterior contacts (Horn et al. 1987). Specific instructions were given on overdenture handling and oral hygiene. The patients were enrolled in an individual dental hygiene program every 6–12 months, either at the University of Amsterdam or at private practices.

Clinical evaluation and outcome measures

The patients were followed up 1, 2, 4, and 8 weeks after implant insertion and 2, 4, and 12 months after insertion of overdentures (baseline). At all visits, a clinical control of mucosa, implants, and overdentures took place and adverse events were noted.

Fig. 1. Individualized laboratory-made radiographic holder attached to the ball anchor.

Radiographic assessments were performed at implant loading and 1 year of follow-up.

The main outcome measures were:

- Implant survival rate
- Peri-implant marginal bone loss

Secondary outcomes were:

- Peri-implant mucosa
- Overdentures

An implant was considered as "surviving implant," if it remained inserted during the observation period (Albrektsson et al. 1986).

Standardized digital radiographs were performed perpendicular to the implant axis with the long-cone technique (Updegrave 1951). For this purpose, laboratory-made individual implant-supported X-ray holders were used which were made on the cast after implant impression (Fig. 1). Two examiners (BH and AZ) evaluated mesial and distal bone levels at implant loading and 1 year using a

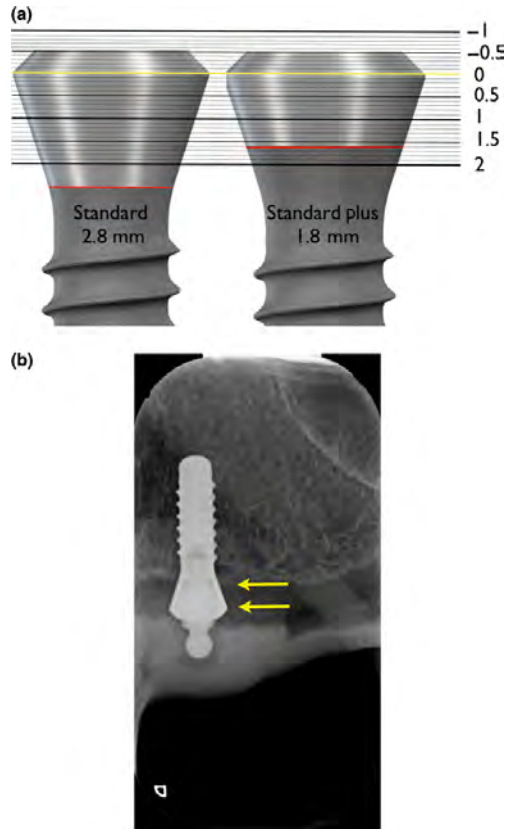


Fig. 2. (a) The distance from the first bone-to-implant contact to the implant shoulder as reference (yellow line) was measured. (b) Standardized radiograph illustrating the measured distance from bone level to implant shoulder as reference (yellow arrows).

Table 1. **Distribution of implants (n) according to type (Standard Plus/Standard), length and region**

	Implant type			Implant length				Implant region						
	SP	S	Total	8 mm	10 mm	12 mm	Total	12	13	14	22	23	24	Total
Implants (n = 38)	15	23	38	1	12	25	38	1	16	2	4	14	1	38

Table 2. **Peri-implant bone loss (mm) at 12 months (mean, standard deviation, median, interquartile range, range). One implant was lost until 12 months (n = 37)**

Bone loss at 12 months	n	Mean (mm)	SD (mm)	Median (mm)	IQR (mm)	Range (mm)
	37	0.7	1.1	0.48	0.56	−2.4–5.8

Table 3. **Bone loss (mm) at 12 months split for implants with and without GBR (mean, standard deviation, median, range)**

Bone loss at 12 months	n	Mean (mm)	SD(mm)	Median (mm)	Range (mm)
Implants with GBR	4	0.9	0.7	0.8	0.1 to 1.8
Implants without GBR	33	0.7	1.1	0.4	−0–7 to 2.8

Table 4. **Bone loss (mm) at 12 months split for patients being smokers and non-smokers (mean, standard deviation, median, range)**

Bone loss at 12 months	n	Mean (mm)	SD(mm)	Median (mm)	Range (mm)
Implants smokers	6	1	1.6	0.4	0.1 to 4.2
Implants non- smokers	13	0.5	0.8	0.5	−0.7 to 2.8

software program (Image J; National Institutes of Health, Bethesda, MD, USA). The distance from the first bone-to-implant contact to the implant shoulder as reference point was measured in 0.1 mm increments (Fig. 2a,b). The known distance between implant threads was used for calibration (1.25 mm). In case of measurement discrepancies of more than 0.5 mm, the radiographs were re-examined and discussed until a consensus was found. Cohen's kappa coefficient was calculated to assess the agreement between the two examiners. Mesial and distal bone loss measurements were averaged per implant. Then, the average of both implants per patient was used for the analysis of bone loss between baseline and 1 year, that is, the unit of the analysis was the patient.

Statistical analysis

Descriptive statistics was applied by calculating means, medians, standard deviations, and interquartile ranges of bone loss. Bone loss from baseline to 12 months was statistically assessed using the Wilcoxon signed rank test. The level of significance was set at 5%.

Results

Patients and implants

In total, forty implants in twenty maxillary edentulous patients (5 women and 15 men) were included in the present study. The mean age of the patients was 61 years (range 45–84 years) at the time of surgery.

Six patients (6 men) were smokers, whereas 14 patients (5 women and 9 men) were non-smokers. One patient (smoker) withdrew from the study due to personal reasons. Consequently, 38 titanium–zirconium implants in nineteen patients were examined at a mean follow-up of 1.1 years (range 1.0–1.7 years).

Primary implant stability was achieved with all implants.

The location and distribution of implant type and length are illustrated in Table 1.

The majority of implants (n = 34) were placed in pristine bone with a flapless approach.

An open flap procedure and simultaneous minor bone augmentation were performed for 4 implants.

Fifteen patients preferred an overdenture with reduced palatal coverage, whereas four patients chose for a full palatal coverage.

In the opposing jaw, fifteen patients had mandibular implant-supported overdentures, 3 patients had complete mandibular dentures, and 1 patient had three remaining natural teeth and a partial denture.

Implant survival

The implant survival rate at 1 year amounted to 97.3%.

One implant failed out of the evaluated 38 implants due to loss of osseointegration 2 weeks prior to the 1-year follow-up visit. This implant was placed flapless without GBR. The patient was occasional pipe smoker and chose for an overdenture with reduced palatal coverage. There was abnormal tooth wear visible 7 months following overdenture insertion indicating parafunctions.

In the lower jaw, the patient was wearing an overdenture on 2 implants and a bar. The patient reported pain when removing the overdenture and was scheduled for a control. The implant was mobile and could be removed manually. The socket was cleaned carefully, and all granulation tissue was removed. A new implant was successfully reinserted at the same location (region 23) after 2 months of healing with minor local GBR.

Marginal bone loss

The inter-rater agreement (Kappa) of the two examiners was κ= 0.82, which corresponds to a very good agreement.

The bone loss is illustrated in Tables 2–5 and Fig. 3 a–d and 4 a–d.

There was significant bone loss at 1 year ($P < 0.01$, 95% CI: 0.28 – 0.95 mm, Wilcoxon signed rank test). Overall, when averaging over implants and patients, the mean bone loss amounted to 0.7 mm (±1.1) and the median bone loss was 0.48 mm (IQR: 0.56 mm).

At the 12-month follow-up, bone loss up till 2 mm was observed around 23 implants (62%). Bone loss of 2–3 mm was found around 1 implant (3%), whereas bone loss of more than 3 mm was identified around 2 implants (5%). In eleven implants (30%), either no bone loss or slight bone gain was evident.

The descriptive bone loss of implants split to the variables GBR, smoking, and overdentures with/without palatal coverage is presented in Tables 3–5.

Peri-implant mucosa

Until 2 months of loading:

- Mucosa overgrowth around 7 implants of 5 patients
- Pain spot in 1 patient

At 2 months of loading:

- Mucosa overgrowth around 3 implants of 2 patients

At 4 months of loading:

- No events

At 1 year of loading:

- Mucosa overgrowth around 1 implant of 1 patient
- Recession around 1 implant of 1 patient

In all patients with mucosa overgrowth, mucosa excisions were performed. In total, 13 soft tissue events occurred at 1 year. Two clinical case examples are presented in Fig. 5a,b.

Overdentures

Until 2 months of loading:

- 1 overdenture tooth 23 fracture (laboratory repair)
- 1 rebasing (direct)

At 2 months of loading:

- 1 fracture of the buccal shield in region of 11–14 (laboratory repair)
- 1 rebasing (direct)
- 1 phonetic problem, palatal coverage thinned out and directly rebased
- 1 patient reports pain when inserting the overdenture in the morning (this patient suffered from mucosa overgrowth)

At 4 months of loading:

- 1 patient reports pain when inserting the overdenture in the morning (same patient as at 2 months)

Between 4 months and 1 year:

- 2 partial overdenture tooth fractures (teeth 11, 12) in 2 patients (direct repair)
- 1 partial direct rebasing
- 1 direct rebasing, 1 indirect rebasing in one and the same patient
- pronounced tooth abrasion and fractured incisors in 1 patient (no repair needed, just polished; this patient lost 1 implant)

At 1 year of loading:

- 1 minor overdenture tooth fracture 22 (no repair needed, just polished)

Overall, there were 4 minor fractures which could be resolved chairside by either polishing or composite buildups and 2 major fractures, which were sent to the dental technician for repair. At 1 year, 5 overdentures were rebased directly chairside. One overdenture was sent to the laboratory for an indirect rebasing.

Discussion

The results of the present study demonstrated a high implant survival rate for 2 maxillary implants supporting overdentures at 1 year of function. There was significant peri-implant bone loss from implant loading to the 1-year follow-up.

Implant survival rate

A lower implant survival rate (82.1%) than in the present study was reported in a study on 2 narrow-diameter implants placed in the canine area of fourteen patients (Weng & Richter 2007). The mean observation period was 25.6 months which is longer than in the present study. Likewise as in the present study, implants were loaded with a conventional approach, that is, 2 and more months following implant placement (Esposito et al. 2007). Conventional implant loading in the edentulous jaw supporting overdentures had a positive impact on implant survival with less implant failures compared with shorter healing times (Schimmel et al. 2014; Kern et al. 2016). Still, there was a high number of failures in the named study even after 7 months of healing before loading.

The overdentures were of similar design as in the present study with a metal framework and open palatal design but supported by 2 telescopic abutments (Weng & Richter 2007). Telescopic abutments are more rigid than ball anchors which might have affected the load transfer to implants and accordingly the implant survival rates in a negative way. On the other hand, there were no differences for the survival rates of 4 maxillary implants supporting overdentures with either telescopic crowns, bar or locator attachments in a prospective study at 3 years (Zou et al. 2013). Unfortunately, there was no random allocation of the 3 attachment systems. One might speculate that the attachment system is not likely to influence implant survival rates when 4 implants are placed in the maxilla, but might have an effect when less than 4 implants are inserted. Furthermore, this might apply primarily for rigid telescopic attachments compared with ball attachments with a higher degree of freedom.

In another study, the patients were randomly assigned to splinted maxillary implants by means of a bar and to unsplinted implants by means of ball attachments (Bergendal & Engquist 1998). Sixteen patients received less than 4 implants in the maxilla. No significant differences were found for the survival of splinted vs. unsplinted implants at 5 years (Bergendal & Engquist 1998). Thus, bar and ball attachments seem not to have an impact on implant survival rates, even when less than 4 implants are placed in the maxilla.

Another study also presented an inferior 1-year survival rate of 84.6% for 3 narrow-

Table 5. **Bone loss (mm) at 12 months for implants supporting overdentures with and without palatal coverage (mean, standard deviation, median, range)**

Bone loss at 12 months	*n*	Mean (mm)	SD(mm)	Median (mm)	Range (mm)
Overdentures with palatal coverage	4	0.1	0.6	0.3	−0.7 to 0.7
Overdentures without palatal coverage	15	0.9	1.2	0.5	−0.1 to 4.2

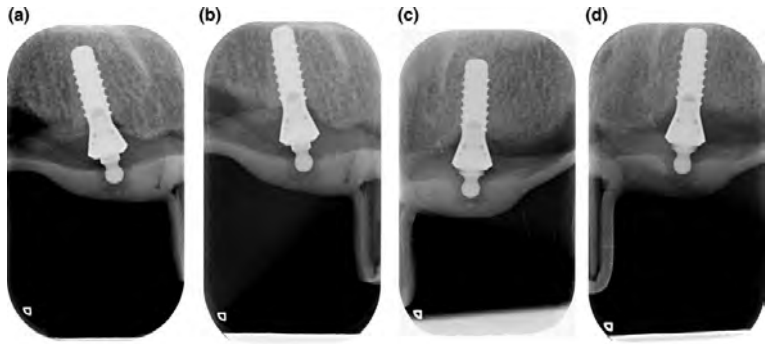


Fig. 3. Two clinical cases illustrating the considerable variations of bone loss from baseline (implant loading) to the 1-year follow-up). (a) Case 1: Bone level of implant 13 at baseline (implant loading). (b) Case 1: Bone level of implant 13 at 1 year of loading. (c) Case 1: Bone level of implant 23 at baseline (implant loading). (d) Case 1: Bone level of implant 23 at 1 year of loading.

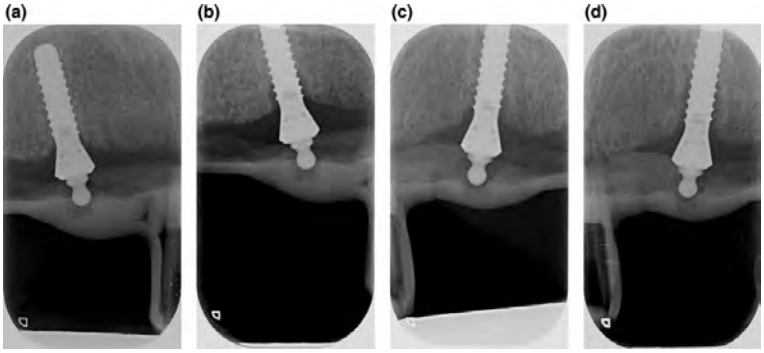


Fig. 4. Two clinical cases illustrating the considerable variations of bone loss from baseline (implant loading) to the 1-year follow-up). (a) Case 2: Bone level of implant 13 at baseline (implant loading). (b) Case 2: Bone level of implant 13 at 1 year of loading. (c) Case 2: Bone level of implant 23 at baseline (implant loading). (d) Case 2: Bone level of implant 23 at 1 year of loading.

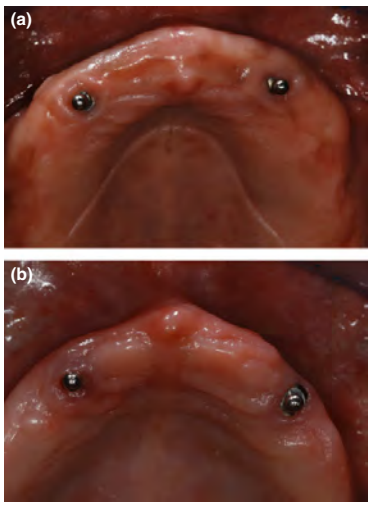


Fig. 5. (a) One-year follow-up of 2 maxillary ball anchors surrounded by healthy mucosa. (b) Mucosa overgrowth around ball anchors at the 1-year follow-up.

diameter implants supporting maxillary overdentures (Payne et al. 2004). In contrast to the present study, all implants were placed in combination with ridge expansion and ridge splitting, a technique not well approved with regard to implant survival rates. On the other hand, only minor GBR was applied in the 4 of 38 study implants for coverage of dehiscence or fenestration defects. The GBR technique is well documented in implant dentistry. A systematic review reports high survival rates of 95.7% (range 84.7% to 100%) at 1–10 years for implants placed with GBR to treat peri-implant dehiscence and fenestration defects in the maxilla (Chiapasco & Zaniboni 2009). Thus, it is unlikely that the applied minor GBR had an influence on the survival rate in the present study. It does not surprise hence that the failed implant was not in conjunction with GBR.

The favorable implant survival rates in the present study should be interpreted with caution though due to the short observation period. The implants are to be monitored over a longer period before this treatment option can be recommended on a large scale. Besides, less than 4 maxillary implants as overdenture support showed a 3 times increased estimated risk for implant loss compared with 4 maxillary implants (2.3 vs. 7.2, $P < 0.0001$) according to a recent systematic review (Kern et al. 2016).On the other hand, it is well known that most implant failures are early failures and occur during initial implant healing, whereas less than 50% of the failures usually correspond to late failures, which happen when the established osseointegration cannot be sustained (Schley & Wolfart 2011).

Peri-implant bone loss

The majority of implants (62%) in the present study showed a maximum bone loss of 2 mm, which is within the range of previously reported implant success criteria (Albrektsson et al. 1986). Three implants in 2 patients (8% of the implants) lost more than 2 mm of bone. Several reasons might have contributed to this finding. These implants were placed flapless without GBR. Still, 1 of these 2 patients had poor initial bone conditions. Bone quality and quantity are often compromised in the maxilla (Chan et al. 1998). Both patients had overdentures with reduced palatal coverage, which might have subjected the implants to biomechanical stress (Rodriguez et al. 2000). The other patient had good initial bone conditions but was smoking 1-package cigarettes per day. Smoking is well known to have a harmful effect and cause more peri-implant bone loss in the maxilla (Vervaeke et al. 2013; Clementini et al. 2014). A current systematic review found smoking to increase the annual rate of bone loss by 0.16 mm/year (Clementini et al. 2014). Furthermore, this patient showed abnormal tooth wear at 7 months indicating parafunctions.

The same implant type and material was used for rehabilitation of the atrophic maxilla in a retrospective study (Cordaro et al. 2013). Ten patients received 4 implants and locator abutments as overdenture support. There was less mean bone loss (0.55 ± 0.5 mm) at a mean observation period of 13.5 months than reported in the present study. Retrospective studies tend to be less critical than prospective ones and often show more favorable outcomes. In addition, the attachment system might have contributed to minor bone loss. An advantage of locator abutments as against to ball anchors with predefined height is the wide range of available locator heights. This enables an optimal choice of the retentive anchor according to the individual mucosa thickness. Therefore, the peri-implant soft tissue support is facilitated and mucosal problems can be prevented. Thirty percent of the implants showed mucosa overgrowth in the present study, inducing a peri-implant mucositis. This might explain the bone loss. The use of locators might have been more advantageous, but due to no available evidence on locators in the edentulous maxilla by the time of study beginning, it was chosen to use the well-proven ball anchors.

Interestingly, some bone loss is evident on the baseline X-rays, that is, from implant insertion to implant loading. A similar observation with a mean bone loss of $1.35 \pm$ 01 mm was found between implant surgery and 12 weeks in a prospective study on 3 maxillary implants supporting overdentures (Ma et al. 2015). In the edentulous, upper jaw positioning of the X-ray is difficult to achieve in a reproducible angle due to the palatal anatomy. To be able to compare bone levels in a standardized way, individual stents were fabricated on the casts after implant impression. Thus, baseline radiographs were taken at prosthesis insertion in the present study, that is, implant loading, which is in agreement with the consensus of the Sixth European Workshop on Periodontology (2008) (Heitz-Mayfield 2008). Considering the questionable benefit of baseline X-rays at the day of implant insertion, it nevertheless would have been interesting to see how much bone was lost during the healing period.

The healing pattern of most implants (88%) was transmucosal. Several studies found no significant difference in bone loss when transmucosal implant healing was compared to submerged implant healing (Ericsson et al. 1997; Astrand et al. 2002; Cecchinato et al. 2004; Hammerle et al. 2012). Those studies base on partially edentulous patients. Transmucosal healing in the edentulous jaw might in turn expose implants to risks such as premature loading through the denture and mucosa overgrowth.

Taking into account the growing elderly population, there is a need of clinical trials to validate the use of freestanding implants supporting maxillary overdentures (Gallucci et al. 2009). Therefore, priority should be given to straightforward, efficient, and minimal-invasive treatment procedures that come along with less surgical risks for the patients (Chiapasco et al. 2009). This might be achieved by the placement of less than 4 implants in the maxilla as overdentures support. To substantiate the treatment concept of only 2 maxillary implants, the present results have to be monitored over a longer period of time and corroborated by more clinical data.

Conclusions

The high short-term implant survival rates suggest that maxillary overdentures supported by 2 implants might be a minimal-invasive treatment alternative worth to be considered in specific patients encountering problems with conventional maxillary dentures. The increased bone loss has to be considered though and might have a negative effect on the clinical long-term outcome of this treatment option. Thus, monitoring over a longer period than 1 year and more clinical studies are needed to prove this treatment option to be successful.

Acknowledgements: The present study was funded by the Academic Center for Dentistry Amsterdam (ACTA), the Netherlands. Institut Straumann AG, Basel, Switzerland, provided the material for the study free of charge. The authors would like to thank Sirarpi Pogosian, Academic Center for Dentistry Amsterdam (ACTA), the Netherlands, for the help with organizing the data. Further thanks go to PhD Bassam Hassan and the department of radiology, Academic Center for Dentistry Amsterdam (ACTA), the Netherlands, for the CBCT scans and evaluation of the radiographic data. Gratitude goes also to Dr. Walter Bürgin, School of Dental Medicine, University of Bern, Switzerland, for the statistics. The authors would furthermore like to thank Martin Bub, master dental technician, and his team from technical laboratory Zutphen (Tandtechnisch Laboratorium Zutphen, Zutphen, the Netherlands) for fabrication of overdentures and radiographic holders. Finally, thanks go to Gisela Müller, Center of Dental Medicine, University of Zurich, Switzerland, for the support with the editing of the manuscript.

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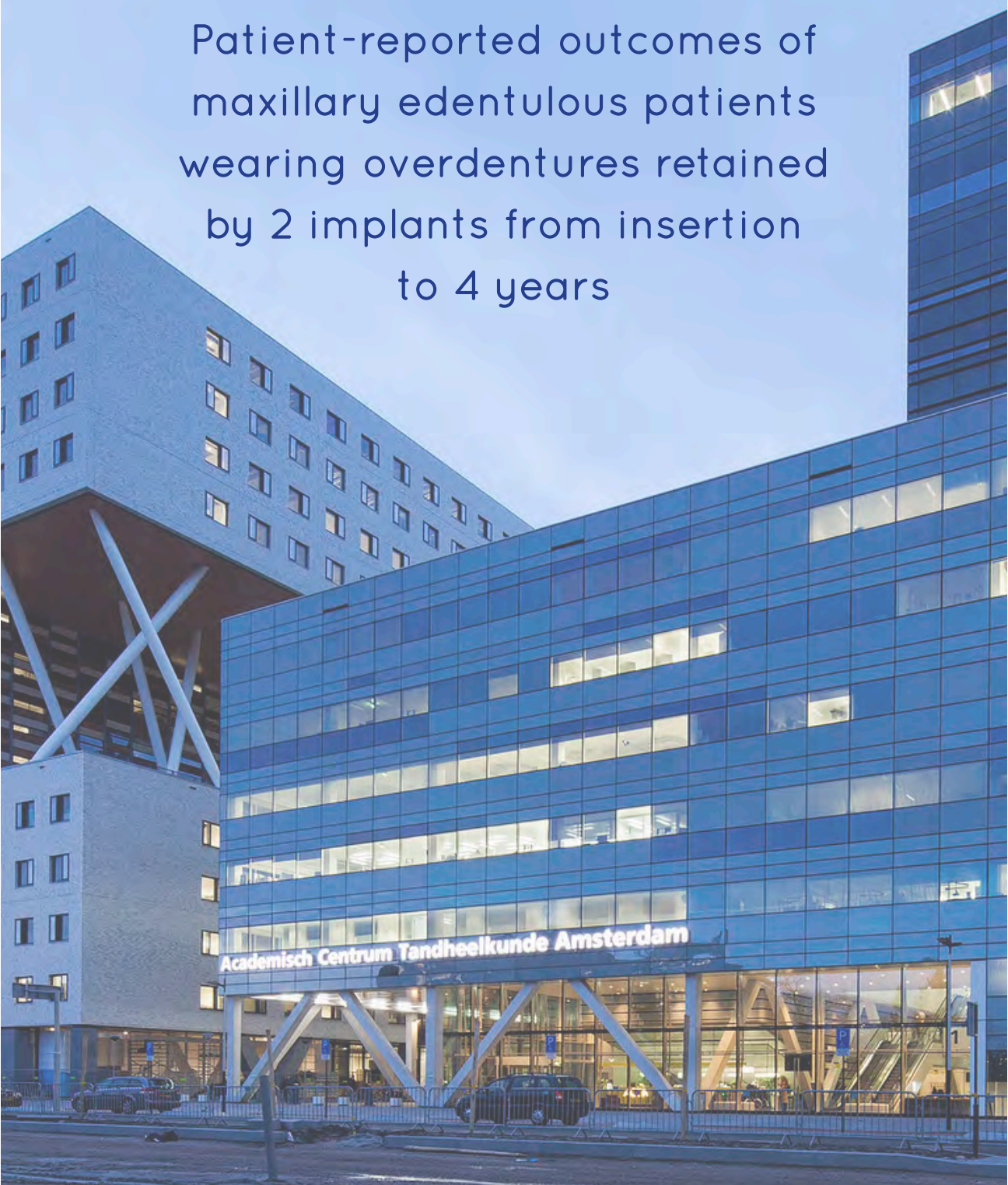
Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. CONSORT 2010 checklist of information to include when reporting a randomised trial.

6

Patient-reported outcomes of maxillary edentulous patients wearing overdentures retained by 2 implants from insertion to 4 years



Patient-reported outcomes of maxillary edentulous patients wearing overdentures retained by 2 implants from insertion to 4 years.

Anja Zembic, PD Dr. Med. Dent[1, 2]/Ali Tahmaseb, PhD[1]/Ronald E. Jung, Prof., Dr. Med. Dent., PhD[2]/ Daniel Wiedemeier, PhD[3]/Daniel Wismeijer, Prof., Dr. Med. Dent[1]

1) Department of Oral Implantology and Prosthetic Dentistry Academic Center for Dentistry Amsterdam (ACTA), Amsterdam, The Netherlands
2) Clinic of Fixed and Removable Prosthodontics and Dental Material Science, Center of Dental Medicine, University of Zurich, Zurich, Switzerland
3) Statistical Services, Center of Dental Medicine, University of Zurich, Zurich, Switzerland

Corresponding address:

PD Dr. Med. Dent. Anja Zembic
Clinic of Fixed and Removable Prosthodontics and Dental Material Science
Center of Dental Medicine
University of Zurich
Plattenstrasse 11
8032 Zurich, Switzerland

phone +41 44 634 32 58
fax +41 44 634 43 05
e-mail: anja.zembic@zzm.uzh.ch

Running head: Patient-reported outcomes for maxillary overdentures

Key words: jaw, edentulous, maxilla, dental implants, patient satisfaction, patient-reported outcomes, quality of life, dental prosthesis, implant-supported, overdenture

Abstract

Objective: This cohort study evaluated patient satisfaction for maxillary implant-retained overdentures (IODs) on 2 implants until 4 years and assessed the treatment effect over time.

Material and Methods: Twenty-one patients encountering problems with their conventional dentures received maxillary IODs on 2 titanium-zirconium implants and ball anchors in the canine area. Patient satisfaction was assessed using the oral health impact profile (OHIP-20E) questionnaires both for dentures and IODs. Two months following insertion of IODs (baseline) the patients chose the preferred overdenture design with full or reduced palatal coverage. OHIP-20E questionnaires were followed according to the individual choice at 1 and 4 years and outcomes were compared to baseline.

Results: Sixteen patients were evaluated at a mean follow-up of 4 years (range 2.4 – 4.8 years). There was no significant difference in the OHIP domains for IODs at 1 year ($OHIP_{total\_1y}$ 9.5, SD 13.0) and 4 years ($OHIP_{total\_4y}$ 14,2, SD 19.1) compared to baseline ($OHIP_{total\_BL}$ 12.4, SD 14.7). Patients were most satisfied with social disability both for IODs ($OHIP_{BL}$: 6.0, SD 7.6 mm; $OHIP_{1y}$: 3.4, SD 5.4; $OHIP_{4y}$: 5.7, SD 9.5) and dentures ($OHIP_{CD\_old}$: 28, SD 29.7 mm; $OHIP_{CD\_new}$ 25.4, SD 28.67 mm). Patients were least satisfied with functional limitation both for IODs ($OHIP_{BL}$: 6.0, SD 7.6 mm; $OHIP_{1y}$: 3.4, SD 5.4; $OHIP_{4y}$: 5.7, SD 9.5) and dentures ($OHIP_{CD\_old}$: 28, SD 29.7 mm; $OHIP_{CD\_new}$ 25.4, SD 28.67 mm).

Conclusions: Patient satisfaction with maxillary IODs on 2 implants did not change from baseline to 4 years and was high at 4 years of function.

Introduction

To evaluate whether or not an implant-retained overdenture (IOD) is a successful treatment, the clinicians usually assess the survival rates of implants and IODs, the peri-implant bone loss and biological, technical and esthetic outcomes. However, for a comprehensive appraisal of the treatment, the patient's satisfaction is of major importance besides the clinician's evaluation.[1,2] The assessment of patient-reported outcome measures (PROMs) by means of questionnaires has gained high importance in clinical investigations and should be considered, since patients and dentists often rate the same parameters differently.[3,4] In a study comparing the assessment of esthetics and phonetics using visual analogue scales (VAS) from patients and clinicians for maxillary IODs, the evaluation was better from the clinicians` perspective.[5] Hence, the patients were more critical and the results indicate that the clinician`s objective assessment does not necessarily represent the patient`s subjective satisfaction. It is a premise though that the patient is satisfied primarily in order to obtain treatment success with an overdenture.[6]

For the patient to be satisfied with an overdenture, several parameters are of relevance. These include retention, stability, phonetics, mastication and esthetics. But also the expectations of a patient to a treatment are of major concern. Furthermore, the patient`s perception of the prosthetic outcome may be influenced by the initial intraoral conditions and health situation.

The oral health is part of the patient satisfaction and influences the quality of life (QoL). The oral health-related quality of life (OHRQoL) is a more comprehensive evaluation than patient satisfaction alone.[7] Thereby, different aspects of life being affected by oral health, such as ability to function, psychological status, social factors, pain and discomfort are determined.[8] Furthermore, the changes of oral health induced by a dental treatment can be measured. The oral health impact profile (OHIP) is an acknowledged questionnaire for the assessment of the OHRQoL and the impact of the prosthetic treatment on the quality of life.[9] The 20-item form OHIP-EDENT is specifically designed for edentulous patients to assess their satisfaction on the prosthetics.[3,10]

OHIP parameters comprising chewing ability and function significantly improved with maxillary IODs compared to conventional dentures.[11,12] These results were based on evaluations at 2 months. It was previously stated that patients develop confidence with removable appliances within 2-4 weeks.[13] A time period of 2 months was therefore defined as an adequate adaption period for assessment of patient satisfaction with new dentures.[14]

Interestingly, patient`s responses may change with time as result of a changed perception of the same parameters. This phenomenon referred to as a response shift shows how OHIP domains that might have been of significance to the patient`s QoL before a treatment, may not be as significant to the patient at a later date.[15] This shift may be due to an adaptation to different circumstances, such as an altered health condition.[15] It can also be caused by external factors, like the adaptation to a treatment being known as a significant treatment effect.

The fact that patients might reply in a different way to PROMs over time is especially of significance in within-subject repeated measures trials, where the effectiveness of a new treatment is tested within the same patient group.

A previous study reported improved VAS ratings from patients for phonetics and comfort at 2 and 6 years compared to the baseline scores with insertion of maxillary IODs supported by 2-6 implants and a bar.[5,16] The authors speculated the improved satisfaction to go along with an additional adaptation to the new situation. There was no information on patient satisfaction before the implant treatment, which reflects a cross-sectional investigation, not a comparison before and after the treatment.[17]

To incorporate the above-mentioned treatment effect, the impact of the treatment should be accounted for when assessing patient satisfaction on different treatment options.[15] For this reason, patient satisfaction should be determined on the original situation i.e. prior to commencement of treatment, too.

The goal of a successful treatment is that the patient stays satisfied over time. Most studies present the outcomes at a certain time. To determine whether the treatment effect of IODs is stable, PROMs should be monitored over time.

The aim of the present prospective within-subject trial was to evaluate the PROMs using OHIP parameters at 4 years of insertion of maxillary overdentures retained by 2 implants and to compare the changes of the scores over time, i.e. to the previously published ones at insertion (baseline) and 1 year.[18]

It was hypothesized that patient satisfaction with maxillary overdentures on 2 implants would be stable over time.

Material and Methods

The present study was designed as a within-subject prospective cohort investigation. The local ethical committee (Medisch Ethische Toetsingscommissie van Vrije Universiteit Medisch Centrum Amsterdam) approved the study protocol and informed written consent was obtained from all patients.

Patients

Twenty-one patients (6 women, 15 men) being dissatisfied with their conventional maxillary dentures were included in the present study. The treatment was executed at the Academic Center for Dentistry Amsterdam (ACTA), The Netherlands by one experienced clinician. The study procedure and inclusion criteria were previously published in detail.[12] Exclusion criteria were patients having more than 4 mandibular abutments (teeth or implants), patients with immediate maxillary dentures, bruxism, systemic disorders in general and in area of planned implant placement and lack of compliance.

Treatment procedure

The original dentures were evaluated for function and esthetics. Adjustments in terms or rebasings and/or relinings of the existing dentures were made in 9 patients. In 12 patients, adjustments would not have been sufficient and new conventional dentures were fabricated. In this way all patients were provided with sufficient dentures according to proven standards.[19] The adjusted or new dentures served as reference for the virtual implant planning and the surgery. Two reduced-diameter implants (Roxolid®, 3.3 mm diameter, Institut Straumann AG, Basel, Switzerland) were inserted in the canine area of the maxilla (corresponding to the canine position of the upper denture) using guided surgery (coDiagnostiX, Dental Wings GmbH, Freiburg, Germany). Following the healing period of 2-4 months, implant impressions were performed using the perforated maxillary denture as impression tray. In this way the intermaxillary relation was simultaneously registered.[20] The dental technician modified the maxillary dentures to IODs with incorporated metal frame and full palatal coverage. Two titanium matrices were indirectly fixed to the overdenture base. The retentive anchors (Retentive anchor abutment, Institut Straumann AG, Basel, Switzerland) were fitted to the implants with a defined torque. A balanced, lingualized

occlusion without anterior contacts in habitual occlusion was achieved. The patients were instructed on proper overdenture handling and oral hygiene measures. During the time of converting the upper denture to the IOD, patients were wearing a provisional upper denture, which was previously fabricated as a duplicate of the existing one.

The IODs were worn for 2 months. Thereafter, the dental technician reduced the palatal coverage until the metal frame in all patients and the altered maxillary IODs were worn for another 2 months. The influence of the palatal coverage on patient satisfaction was assessed in another study.[21] Subsequently, each patient selected the overdenture design of preference. Seventeen patients chose to continue wearing the IOD with reduced palatal coverage, 4 patients preferred an IOD with full palatal coverage. The IODs were sent for modification to the in-house dental lab at the day of the clinical visit. Further follow-ups were performed at 1 year and 4 years of IOD insertion.

Patient-reported outcomes

Patient-reported outcomes were achieved for existing (old) dentures prior to any adjustment and for new conventional dentures to assess the pre-treatment satisfaction (previously published[12]). In addition, PROMs were assessed for IODs to assess the satisfaction following implant treatment and the changes were statistically analyzed over time. For that purpose, patients responded to OHIP-20E questionnaires in Dutch language at time of study inclusion and 2 months following insertion of new dentures. The same OHIP questionnaires were used 2 months following insertion of maxillary IODs with palatal coverage and 2 months following insertion of IODs with reduced palatal coverage. Thereafter, the patients chose the preferred overdenture design and OHIP-20E questionnaires were answered by the patients for IODs either with full or reduced palatal coverage according to the individual choice at 1 year and at 4 years.

The questionnaires used visual analogue scales (VAS) with a horizontal line of 100 mm. On the left end the anchor word “never” represented 100% satisfaction and on the right end the anchor word “always” represented 0% satisfaction. Consequently, higher mm values represented a reduced patient satisfaction. Each patient expressed per question the individual appraisal of satisfaction by placing a vertical stripe on the horizontal line. The stripe was then measured in mm. The 20 questions

accounted for the 7 OHIP domains: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. The results of the OHIP questionnaires for IODs were statistically evaluated for the 3 timepoints 2 months, 1 year and 4 years.

Statistical analysis

The Pairwise Wilcoxon signed rank test was applied for the comparison of OHIP scores at the different timepoints baseline (i.e. 2 months following insertion), 1 year and 4 years following insertion of maxillary IODs. The patients were grouped at baseline according to the preferred overdenture design (IODs with full or reduced palatal coverage) for the statistical evaluation and proper comparison of patient satisfaction on the 2 different IOD designs over time.

At the 4-year follow-up the OHIP scores were compared by means of the Wilcoxon rank sum test for overdentures with full and reduced palatal coverage. The statistical significance was set at $p \leq 0.05$.

The Wilcoxon signed-rank and rank sum tests were calculated with the software R (https://www.R-project.org/).[22]

Mean OHIP scores were illustrated descriptively per domain for each patient according to the treatment (conventional old dentures, conventional new dentures, IODs at baseline, 1 and 4 years).

Results

Sixteen patients (6 women, 10 men) were evaluated at a mean follow-up of 4 years (range 2.4 – 4.8 years). Two patients were followed-up at 2.4 and 2.5 years, all remaining patients were controlled at more than 4 years following insertion of IODs.
The mean age of the patients at study inclusion was 63 years (range 52-81 years).
There were 5 drop outs of the patients in total (1 patient was abroad and not able to attend the follow-up visit; 1 patient chose to withdraw from the study; 1 patient received new overdentures within another study by his dentist, thus only the implants were followed-up, not the overdenture anymore; 2 patients had implant failures).
Twelve patients (5 women, 7 men) chose for an IOD with reduced palatal coverage (Figures 1-3), whereas 4 patients (1 women, 3 men) chose for a closed palatal coverage. The mean OHIP scores with standard deviation for maxillary IODs at baseline, 1 year and 4 years are shown in Table 1.
There were no statistically significant different OHIP values for any domain at baseline compared to 1 year and 4 years. From baseline to 1 year there was a trend for an increase in patient satisfaction for functional limitation, physical disability, psychological disability, social disability and handicap (evident as decreasing values). From 1 year to 4 years there was a slight decrease in patient satisfaction for all 7 OHIP domains (apparent by increasing values).
Still, patient satisfaction was higher at 4 years (lower OHIP scores) compared to baseline for physical disability, psychological disability, social disability and handicap.
The lowest values, i.e. the greatest patient satisfaction, were found for social disability at all follow-ups (OHIP at baseline: 6.0, SD 7.6 mm; at 1 year: 3.4, SD 5.4; at 4 years: 5.7, SD 9.5)
The highest values, i.e. the lowest patient satisfaction, were evident for functional limitation at all follow-ups (OHIP at baseline: 20.6, SD 18.9 mm; at 1 year: 17.6, SD 18.4; at 4 years: 24.7, SD 23.8).
The comparison of IODs with full and reduced palatal coverage at 4 years revealed no significant differences for all OHIP domains (Table 2). There was a trend for a greater patient satisfaction with full palatal coverage for psychological discomfort, physical disability, psychological disability, social disability and handicap (smaller values). In contrast, patients with a reduced palatal coverage were more satisfied with regard to functional limitation and physical pain.

Figures 4-10 illustrate the progress of patient satisfaction for each OHIP domain subdivided into different prosthesis types (old conventional dentures, new conventional dentures, IODs in the course of time) per patient. The mean OHIP scores with standard deviation for old and new conventional dentures as previously published[12].

Discussion

Even though there were no significant differences in patient satisfaction on maxillary IODs at 1 and 4 years compared to baseline, there was an improved OHRQoL with regard to physical, psychological and social disability and handicap at 1 and 4 years. Consequently, the treatment effect of maxillary IODs was stable until 4 years and the hypothesis could be confirmed.

From 1 year to 4 years the patient satisfaction slightly decreased for all OHIP subgroups. Social disability was rated best at all follow-up visits, whereas functional limitation showed the poorest patient satisfaction at all visits.

Patient satisfaction improved with maxillary IODs in contrast with conventional dentures, indicating a positive treatment effect of implants on the patient satisfaction.

Patient satisfaction overall

In the present study the patients did not have a special preference to the treatment, which might have had a positive impact on the highly rated patient satisfaction in general. Compared to conventional dentures, the patients perceived IODs as a significant benefit for all OHIP domains.[12]

Significantly improved OHIP domains were also reported for maxillary IODs on 3 implants in a similar study compared to conventional dentures.[23]

The attitude and expectation of patients towards a treatment influences their perception of satisfaction. A previous study found more speech problems in edentulous patients that were planned for a maxillary fixed reconstruction on implants but received an IOD, compared to those that were planned for and received an IOD.[24] Patients wishing for a fixed reconstruction tend to be less satisfied with removable appliances on implants than those with no preference.[5] It is known that the magnitude of improvement in OHRQoL is influenced by whether the patient receives the treatment of choice or not.[25] Patients preferring maxillary IODs showed the highest satisfaction compared to those who received new conventional dentures instead.[25]

Potential influencing factors

In addition, the period of edentulism is of relevance. Patients who have been edentulous for a longer period tend to be more satisfied with an IOD in contrast to

patients being edentulous since a short time.[26] Since the present patients were edentulous for several years, the high patient satisfaction is explicable.
The results of the present study and others indicate that the number of implants does not appear to affect patient satisfaction, when the patients were wearing conventional dentures before.[23,27] Furthermore, patient satisfaction on maxillary IODs seems not to be impaired by the attachment system either.[26]

On the other hand, patient satisfaction with implant prostheses might be impaired with the occurrence of prosthetic complications. In the present study, there were several complications until 1 year.[18] This finding confirms the common observation that complications occur most often in the first year.[28]

A higher incidence of mechanical problems for maxillary IODs without palatal coverage was described.[28,29] In the present study allocation to the overdenture design (with full or reduced palatal coverage) was not randomized and the numbers of patients were not equally distributed. The comparison of OHIP parameters between the two overdenture designs therefore gives only a trend and should be interpreted with caution.

In the present study, only patients with a maximum of 4 mandibular abutments were included to prevent a harming effect of antagonistic teeth on the 2 implants in the maxilla (and consequently on IODs). A review article concluded that antagonistic teeth might negatively affect implant survival for maxillary IODs.[30] A recent study did not find a detrimental effect of antagonistic teeth when 6 maxillary implants were connected with a bar, even until 5 years.[31]

The degree of satisfaction should be evaluated critically, because the patients might have systematically overestimated it. This would create a ceiling effect, which was discussed as a disadvantage of PROMs.[32] An initial enthusiasm of the patients when assessing the IODs cannot be precluded. The present 4-year follow-up might have reduced the bias in assessing patient satisfaction. On the other hand, a longer follow-up would be preferable to attain more reliable results. It is assumable, that the occurrence of pathologies or complications would have a detrimental effect on the patient`s satisfaction on IODs.

Patient satisfaction from baseline to 1 year and 4 years

In agreement with the present results, there were no significant differences in OHIP-20 scores for maxillary IODs on 3 implants at 1 and 2 years compared to baseline.[23] Thus, patient satisfaction seems to change insignificantly over a short time.

The amount of patients preferring a reduced palatal coverage (77%) at 2 years was similar to the present results (75%) at 4 years.

A systematic review on patient satisfaction with IODs supports improvements seen after 1 year to be stable for the first 5 years, despite a slight decrease.[33] Unfortunately only 3 studies on maxillary IODs were included, whereby these outcomes can mainly be applied for mandibular IODs. A slight decrease of OHIP parameters from 1 year to 4 years was also evident in the present study. This might be due to the adaptation of the patient to the treatment. Besides, wear occurs with time, which might necessitate adjustments and reduce retention and stability of IODs.

The fact that physical, psychological and social disability and handicap improved at 1 year and 4 years compared to baseline points to an enhanced well-being with maxillary IODs on 2 implants. This might be the result of adaptation, a safer feeling with regard to overdenture retention and gain in confidence.

Social disability

The OHRQoL monitores the outcomes of clinical interventions and thereby enables the evaluation of the patient`s responsiveness to change.[25]

An adequate adaption period should be taken into account when assessing PROMs, which was accounted for in the present study.[17] Accordingly, the patients were likely to be familiar with their maxillary IODs and less limited in social abilities, represented in the highly rated scores for social disability.

Functional limitation

The finding that functional limitation was rated worst at all follow-up visits, shows that some difficulty of chewing was apparent with maxillary IODs on 2 implants. Even though, function did not worsen until 4 years and the scores at 4 years (24.7, SD 23.8) indicate a rather high patient satisfaction of 75%. This might derive from the

fact that patients develop confidence with oral rehabilitation after 2-4 weeks, especially with removable appliances.[13]

The comparison with full (27.3, SD 31.9) and reduced (23.9, SD 22.1) palatal coverage revealed no significant difference for functional limitation at 4 years. Surprisingly, the patients rated function slightly less satisfactory with a full palatal coverage of the IOD. One might assume a better retention and stability of the overdenture when the palate is fully covered. On the contrary, it was found that stability and choice of food were not altered by reduction of the palatal coverage in IODs on 4 implants.[11]

While evidence supports the use of implants in the mandible to improve the oral health status, the standard of care can still not be defined for the edentulous maxilla.[34] According to the results of a systematic review, the use of 2 implants in the maxilla does not compromise patient satisfaction.[35] Considering the continuous population growth the amount of elderly patients will likely increase in future and so probably the need for IODs with a minimal number of implants.[36 37]

Conclusions

Maxillary implant-retained overdentures on 2 implants showed a stable treatment effect over a 4-year period and a high OHRQoL using OHIP-20 could be maintained.

Acknowledgements

This study was partly funded by the Academic Center for Dentistry Amsterdam (ACTA), Netherlands. Implant materials were supplied free of charge by Straumann, Basel, Switzerland.

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Figure 1

Occlusal view of two maxillary implants retaining an overdenture at 4 years. Mucosa impressions are visible from the overdenture with reduced palatal coverage.

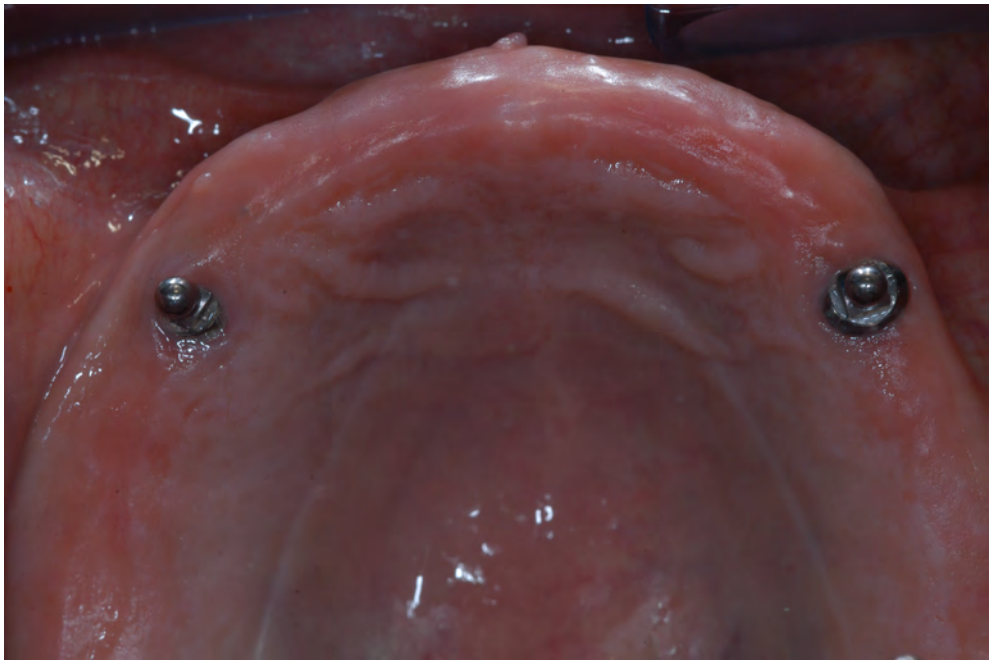


Figure 2

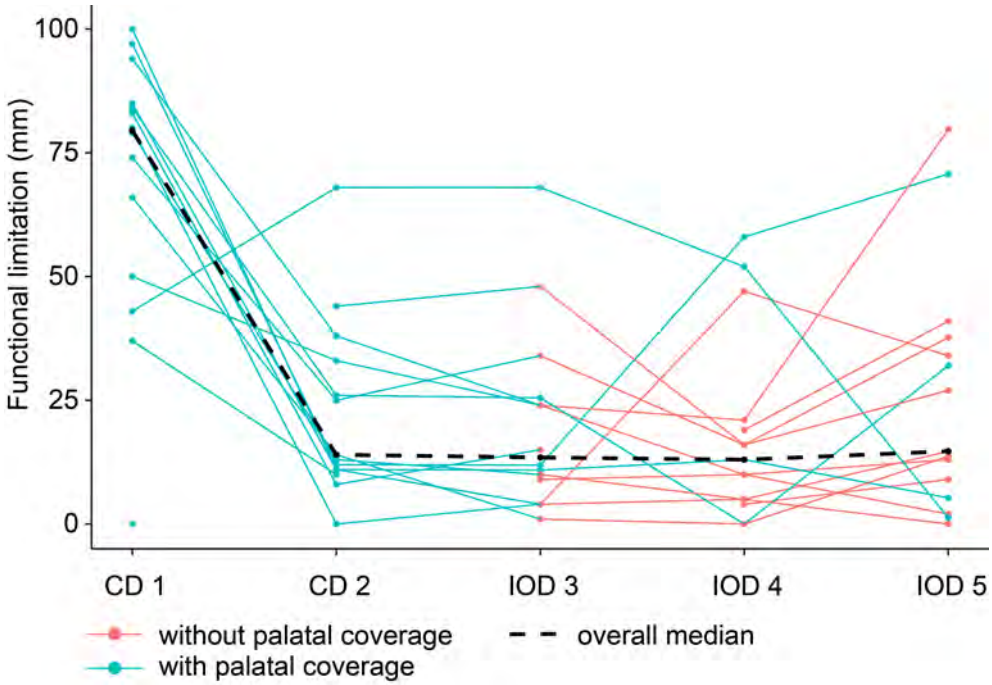
Occlusal view of a maxillary overdenture with reduced palatal coverage at 4 years.

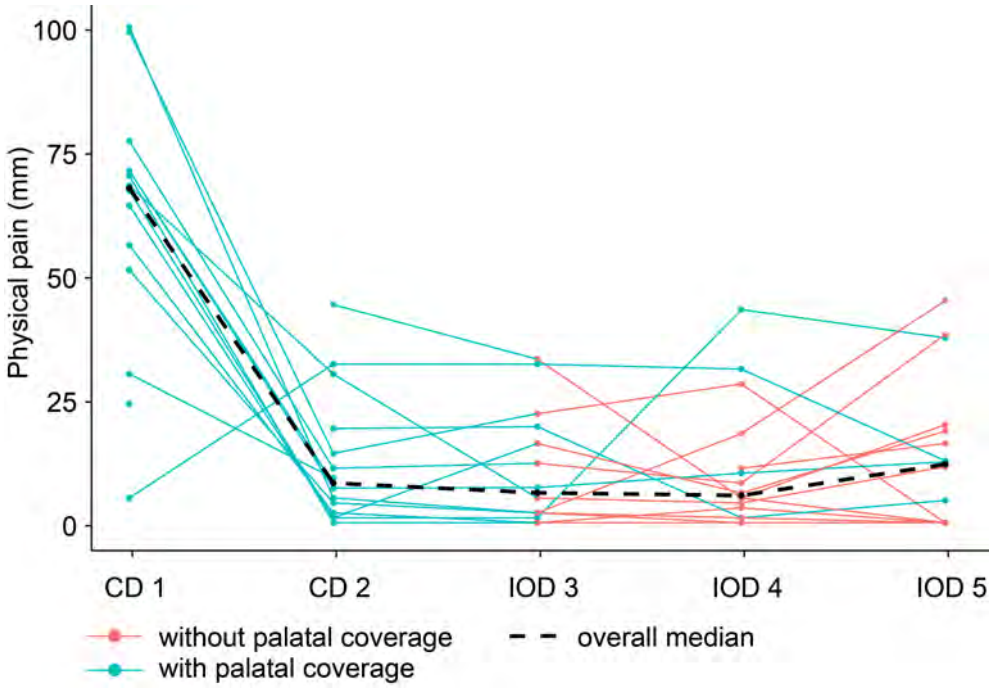
Figure 3

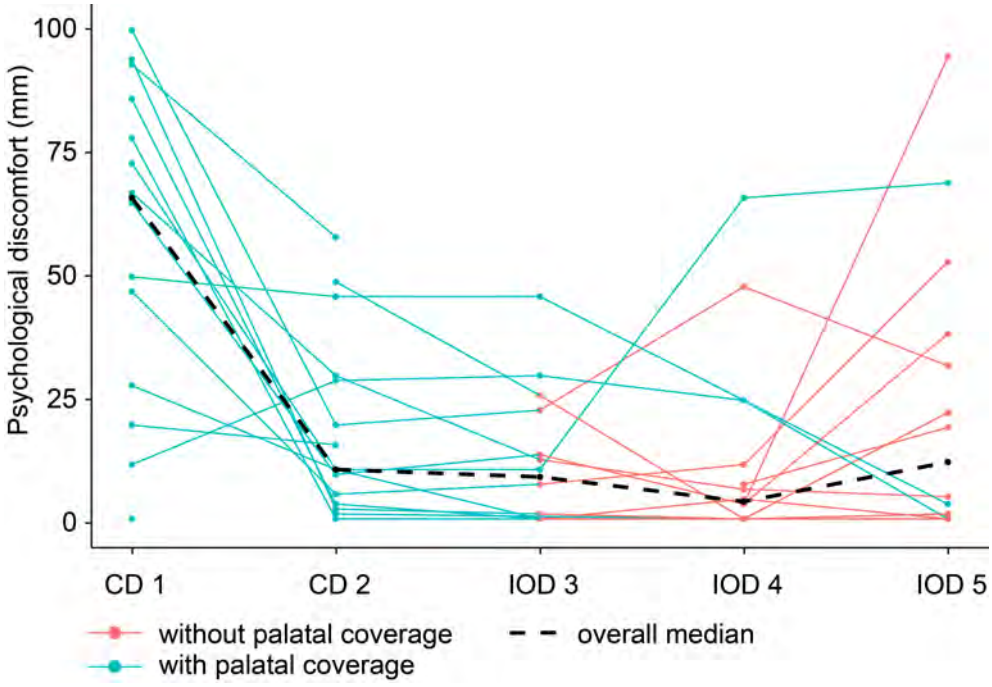
Basal view of a maxillary overdenture with reduced palatal coverage at 4 years.

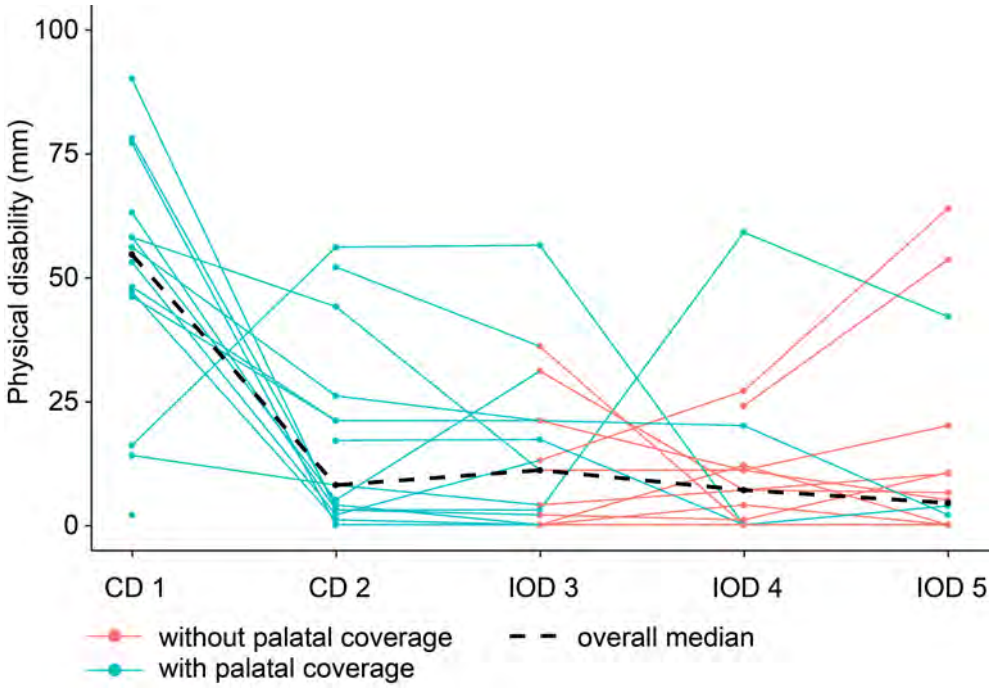
Figures 4-10:

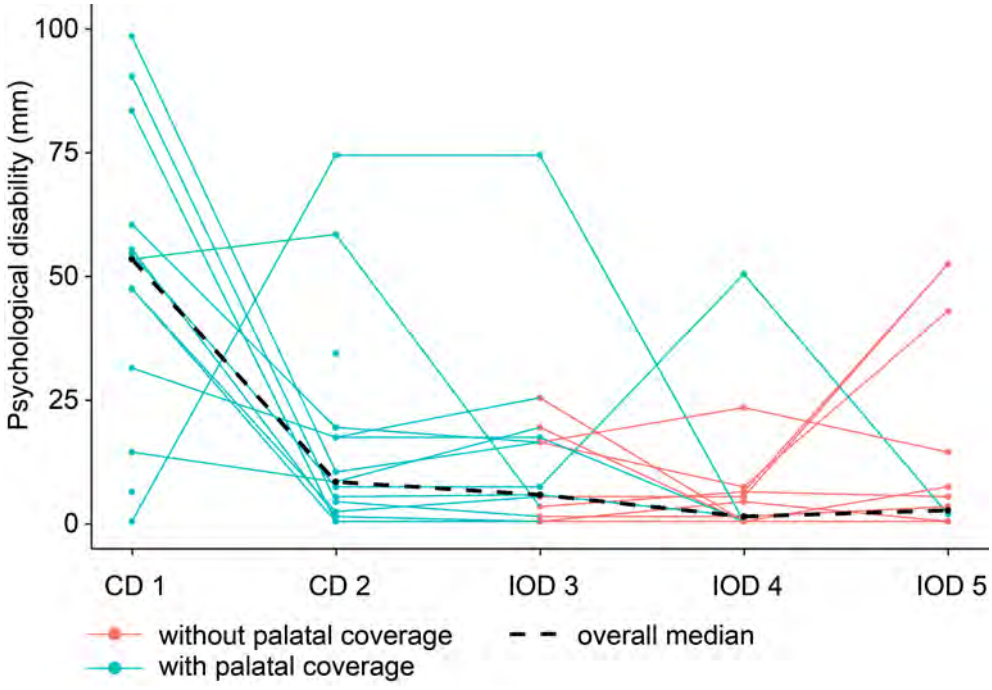
Development of patient satisfaction for each OHIP domain per patient and different prosthesis type (CD 1 = old conventional denture, CD 2 = new conventional denture, IOD 3 = implant-retained overdenture 2 months post insertion, IOD 4 = implant-retained overdenture 1 year post insertion, IOD 5 = implant-retained overdenture 4 years post insertion).

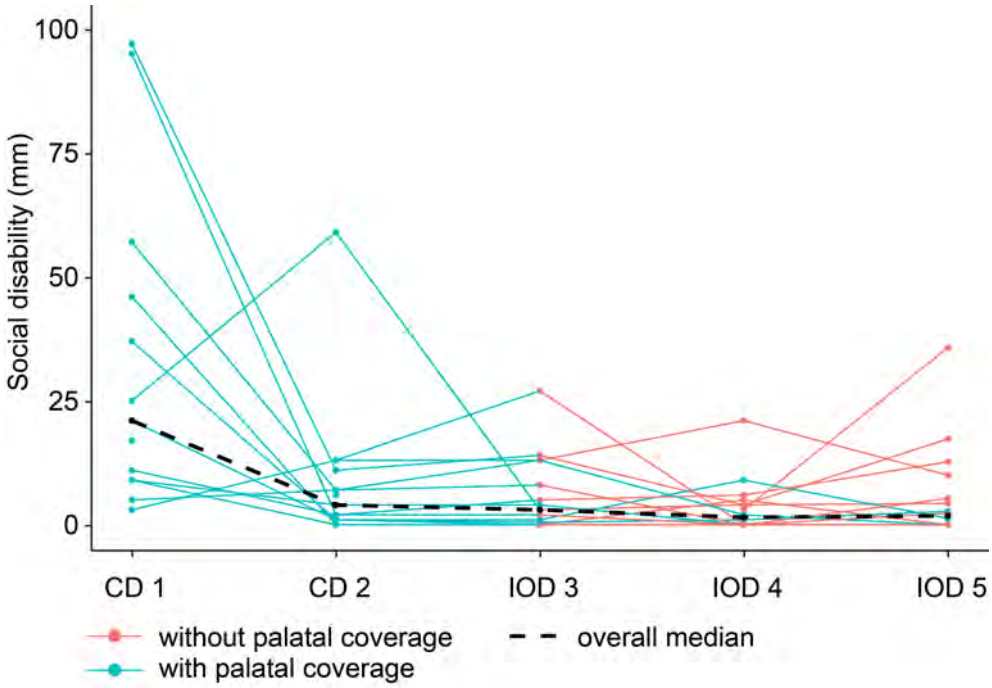



Physical pain (mm)
100
75
50
25
0
CD 1
CD 2
IOD 3
IOD 4
IOD 5
without palatal coverage
with palatal coverage
overall median


Psychological discomfort (mm)
100
75
50
25
0
CD 1
CD 2
IOD 3
IOD 4
IOD 5
without palatal coverage
with palatal coverage
overall median


Physical disability (mm)
100
75
50
25
0
CD 1
CD 2
IOD 3
IOD 4
IOD 5
without palatal coverage
with palatal coverage
overall median


Psychological disability (mm)
100
75
50
25
0
CD 1
CD 2
IOD 3
IOD 4
IOD 5
without palatal coverage
with palatal coverage
overall median


Social disability (mm)
100
75
50
25
0
CD 1
CD 2
IOD 3
IOD 4
IOD 5
without palatal coverage
with palatal coverage
overall median

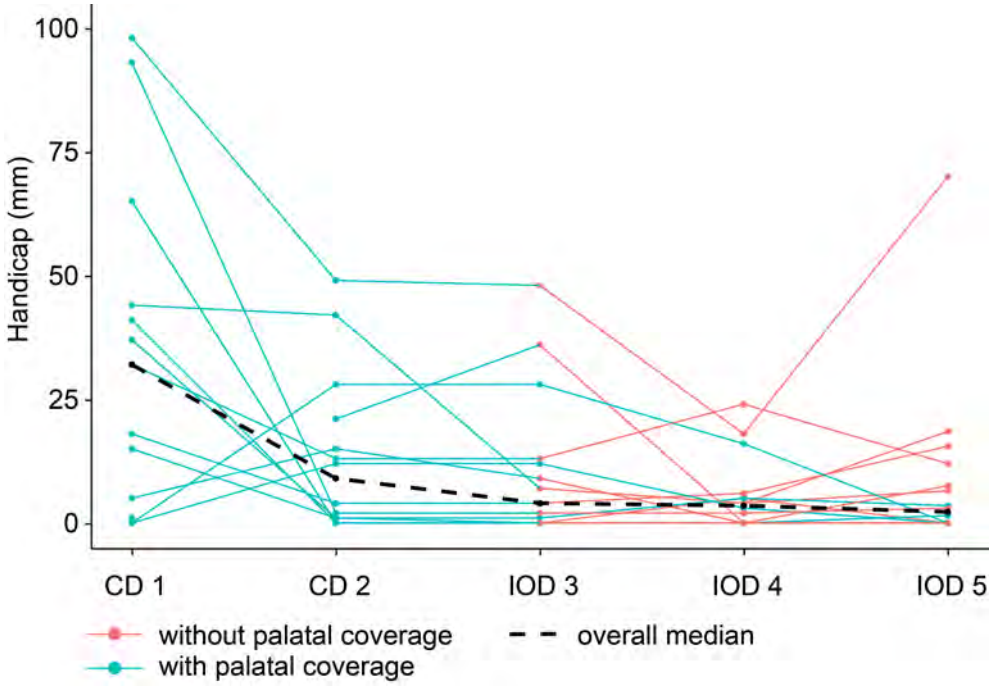

Handicap (mm)
100
75
50
25
0
CD 1
CD 2
IOD 3
IOD 4
IOD 5
without palatal coverage
with palatal coverage
overall median

Table 1: Mean values (mm) and standard deviations (SD) of OHIP domains for maxillary implant-supported overdentures at baseline (BL, n=15) 1 year (1y, n=16) and 4 years (4y, n=16). Lower values values correspond to higher patient satisfaction.

	Functional limitation	Physical pain	Psychological discomfort	Physical disability	Psychological disability	Social disability	Handicap
BL-1y	p=0.4	p=0.83	p=0.66	p=0.56	p=0.26	p=0.41	p=0.22
Mean BL	20.6	10.9	11.7	14.4	12.5	6.0	10.6
SD BL	18.9	11.7	13.8	16.6	19.0	7.6	15.0
BL-4y	p=0.8	p=0.72	p=0.48	p=0.56	p=0.40	p=0.56	p=0.76
Mean 1y	17.6	10.9	12.0	11.3	6.3	3.4	5.3
SD 1y	18.4	12.8	19.0	15.4	12.9	5.4	7.3
1y-4y	p=0.16	p=0.47	p=0.26	p=0.91	p=0.54	p=0.5	p=0.69
Mean 4y	24.7	13.4	22.1	13.6	11.3	5.7	8.6
SD 4y	23.8	15.0	28.2	20.7	19.1	9.5	17.4

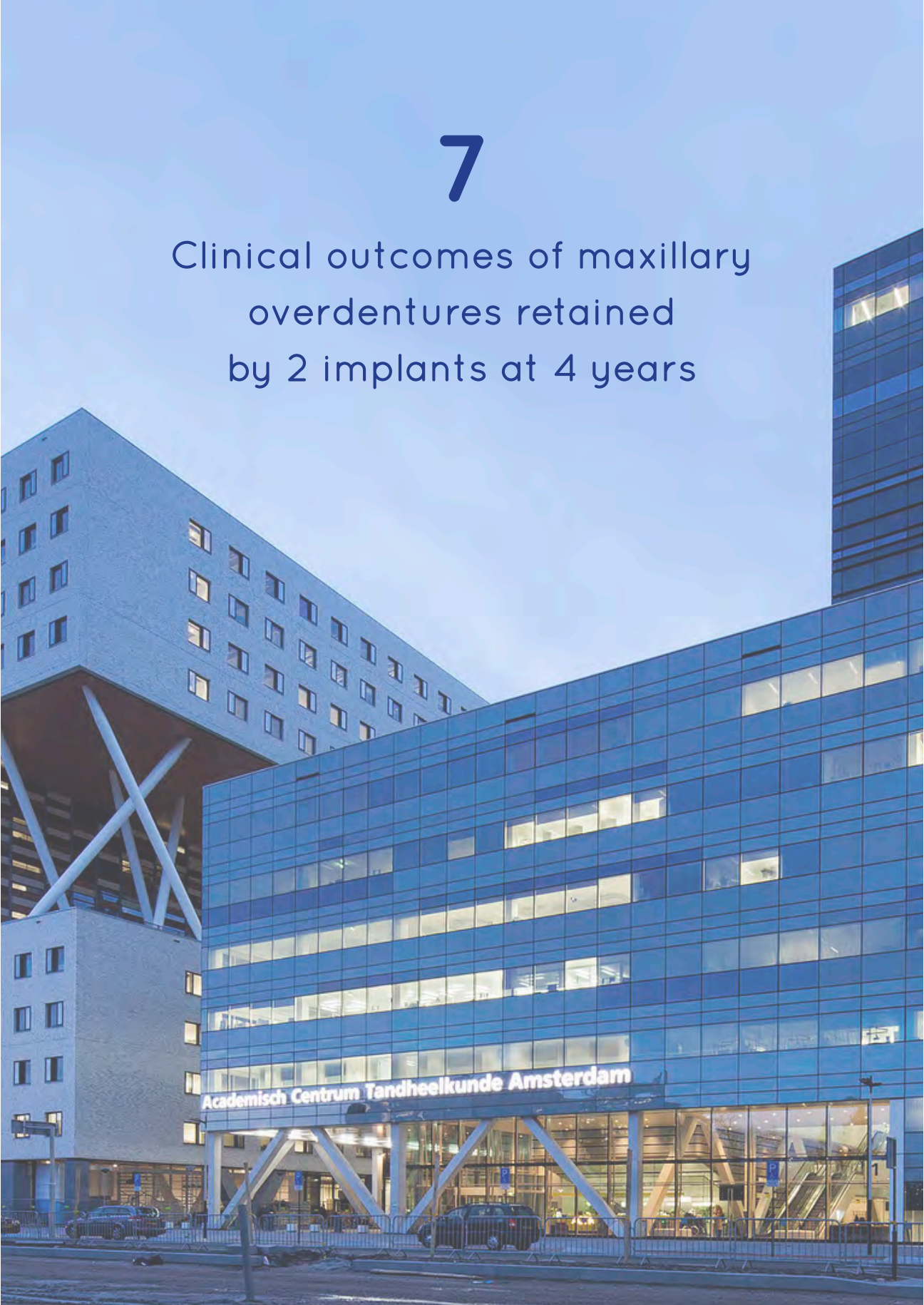
Table 2: Mean values (mm) and standard deviations (SD) of OHIP domains for maxillary implant-supported overdentures with reduced palatal coverage (IOD_0, n=12) and with full palatal coverage (IOD_1, n=4) at 4 years (n.s.).

	Functional limitation	Physical pain	Psychological discomfort	Physical disability	Psychological disability	Social disability	Handicap
Mean IOD_0	23.9	12.4	23.4	14.1	14.6	7.3	11.1
SD IOD_0	22.1	15.8	27.8	21.8	21.2	10.6	19.7
p-value	p=0.86	p=0.49	p=0.67	p=0.90	p=0.31	p=0.34	p=0.34
Mean IOD_1	27.3	16.6	18.0	11.9	1.1	1.0	1.3
SD IOD_1	31.9	14.2	33.4	20.1	1.4	1.3	1.7

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

7

Clinical outcomes of maxillary overdentures retained by 2 implants at 4 years



Clinical outcomes of maxillary overdentures retained by 2 implants at 4 years.

Anja Zembic[§¥], Ali Tahmaseb[¶], Ronald, E. Jung[°], Daniel Wiedemeier [Φ], Christoph, H.F. Hämmerle[⌘], Daniel Wismeijer[♯]

[§] PD Dr. Med. Dent., PhD student, Department of Oral Implantology and Prosthetic Dentistry, Academic Center for Dentistry Amsterdam (ACTA), Move Research Institute, Amsterdam, The Netherlands

¥ Senior teacher and research assistant, Clinic of Fixed and Removable Prosthodontics and Dental Material Science, University of Zurich, Zurich, Switzerland

[¶] Associate professor, PhD, Department of Oral Implantology and Prosthetic Dentistry, Academic Center for Dentistry Amsterdam (ACTA), Move Research Institute, Amsterdam, The Netherlands

[°] Professor, Dr. Med. Dent., PhD, Clinic of Fixed and Removable Prosthodontics and Dental Material Science, University of Zurich, Zurich, Switzerland

[Φ] PhD, Statistician, Statistical Services, Center of Dental Medicine, University of Zurich, Zurich, Switzerland

[⌘]Professor, Dr. Med. Dent., Chairman, Clinic of Fixed and Removable Prosthodontics and Dental Material Science, University of Zurich, Zurich, Switzerland

[♯]Professor, Dr. Med. Dent., Department of Oral Implantology and Prosthetic Dentistry, Academic Center for Dentistry Amsterdam (ACTA), Move Research Institute, Amsterdam, The Netherlands

Keywords: dental implants, titanium-zirconia, diameter reduced, overdenture, jaw, edentulous, maxilla

Running head: 4-year results of maxillary overdentures on 2 implants

Address for correspondence:

PD Dr. Anja Zembic

Clinic of Fixed and Removable Prosthodontics and Dental Material Science

University of Zurich
Plattenstrasse 11
8032 Zurich, Switzerland
Phone: +41 44 634 32 60
Fax: +41 44 634 43 05
E-mail: anja.zembic@zzm.uzh.ch

Abstract

Objective: To evaluate implant survival rates and peri-implant bone loss of 2 titanium-zirconium implants retaining maxillary overdentures at 4 years.

Material and Methods: Twenty-one maxillary edentulous patients (6 women, 15 men) experiencing problems with their complete dentures were included. Each patient received 2 diameter-reduced titanium-zirconium implants in the anterior maxilla. Following conventional healing, overdentures with metal frame were inserted on two ball anchors. Implants and overdentures were assessed at insertion (baseline) and 4 years. Implant survival rates and bone loss were primary outcomes. Bone levels were assessed with standardized radiographs. Secondary outcomes encompassed technical and biological complications.

Results: Fourteen patients with twenty-six implants were analyzed at a mean follow- up of 4 years (range 3.6 – 4.2 years). There were 5 implant failures in 4 patients, resulting in a cumulative survival rate of 75%. There was significant bone loss from baseline to 4 years (mean mesial 0.9 mm ± 1.5; mean distal 1.0 mm ± 1.3 mm). Seventeen matrices were mobile in 10 patients and 30 metal springs were lost or broken in 7 patients (several repeated events). There was 1 implant with mucositis.

Conclusions: Maxillary overdentures on 2 implants should only be applied as minimal invasive treatment in specific situations due to low implant survival rates and a high amount of technical complications.

Introduction

The prevalence of edentulism is varying worldwide with the tendendy of a decrease (Mojon et al. 2004; Osterberg et al. 1995; Petersen et al. 2005; Samson et al. 2008; Turkyilmaz et al. 2010). Nonetheless, the need for treatment of edentulism will persist in future (Christensen et al. 2009). It might happen that patients get older when becoming edentulous in case of a regular plaque control program and thereby long lasting tooth preservation (Axelsson et al. 2004). But also the increase in life expectancy can contribute to this shift of patients becoming edentulous at an old age. This trend can be seen in Switzerland, where it was reported that 40% of the edentulous patients are 85 years or even older (Zitzmann et al. 2008).

A conventional denture represents the standard treatment for edentulous patients. When compared to an implant overdenture in the maxilla, it was found that patient satisfaction did not necessarily enhance with implant overdentures (de Albuquerque Junior et al. 2000). The authors concluded that maxillary conventional dentures should be considered as standard care when bone conditions are good. In case of poor bone conditions in contrast, patients can encounter problems with maxillary dentures in terms of insufficient retention and stability. In these situations, implants may often represent the only possibility to enhance patient satisfaction. Today, the economical situation affects patients worldwide. Usually, the costs for removable implant prostheses are lower than for fixed implant prostheses (Stoumpis & Kohal 2011). Even though, patients often refuse implant treatment, especially when being older, due to fear of the surgery and costs for the treatment (Ellis et al. 2011; Walton & MacEntee 2005; Zitzmann et al. 2007). For the edentulous mandible, the standard treatment was defined to be an overdenture on 2 implants (Feine et al. 2002). For reasons of cost-effectiveness, sufficient evidence suggests even an overdenture on 1 implant in the mandible to be an adequate solution for geriatric patients (Alqutaibi et al. 2017; Bryant et al. 2015; Cordioli et al. 1997; Gonda et al. 2010). With regard to the rehabilitation of the edentulous maxilla a high number of implants ranging from 8 to 10 was used in the past. The introduction of rough surface implants lead to increased implant survival rates and both implant healing times and the amount of implants could be reduced (Wennerberg & Albrektsson 2010). When 4 maxillary implants were compared to 6 maxillary implants, the bone resorption was similar at 5 years (Slot et al. 2016). In addition, there was no significant difference with regard to implant survival whether 4 or 6 implants were used in the maxilla (100% vs. 99%)

(Slot et al. 2016). Consequently, 4 implants are nowadays considered an adequate number for retention of a maxillary overdenture. Interestingly, it was found that patient satisfaction seems not to depend on the number of implants for maxillary overdentures (De Bruyn et al. 2015). Less invasive treatment opportunities are gaining significance recently. There are several studies concluding that 3-implant overdentures might be an acceptable approach for the edentulous maxilla (strict patient selection provided) (Al-Zubeidi et al. 2012; Ma et al. 2016; Mo et al. 2016; Payne et al. 2004). In general, the ideal number of implants for the edentulous maxilla depends on multiple factors and is difficult to define (Roccuzzo et al. 2012). There is little scientific evidence on less than 4 maxillary implants as overdenture retention. Consequently, more research should focus on straightforward, little invasive and cost-effective treatment options for maxillary edentulous patients. Taking into account the economical situation today, it would be interesting to know, whether the same successful outcomes as for 2 implants in the edentulous mandible can be achieved for 2 implants in the edentulous maxilla. It was assumed that the use of only 2 maxillary implants may not compromise implant suvival rates or patient satisfaction (Laurito et al. 2012). The aim of this prospective within-subject trial was therefore to assess the clinical results of maxillary overdentures on 2 implants at 4 years of function.

Material and Methods

The present study is a follow-up of the previously published 1-year outcomes (Zembic et al. 2016). The local ethical committee approved the study protocol and informed written consent was obtained from all patients.

Patients

Twenty-one patients (6 women, 15 men) being dissatisfied with their conventional dentures were included in the present study. The mean age at study inclusion was 63 years (range 52-81 years). All treatment steps were executed at the Academic Center for Dentistry Amsterdam (ACTA), The Netherlands by one experienced clinician. The study procedure was previously published in detail (Zembic & Wismeijer 2013).

Exclusion criteria were patients having more than 4 mandibular abutments (teeth or implants), patients with immediate maxillary dentures, bruxism, systemic disorders in general and/or in area of planned implant placement and lack of compliance.

Pretreatment and surgical procedure

The original dentures were evaluated for function and esthetics and new conventional dentures were fabricated in 12 patients. Adjustments of the existing dentures were made in the remaining 9 patients. In this way all patients were provided with sufficient dentures according to proven standards (Zarb & Jacob 2004). These dentures served as reference for the digital implant planning and implant placement. A cone beam computed tomography (CBCT)-scan (NewTom 5G, QR, Verona, Italy) was made and implants were planned in canine position preferably (coDiagnostiX, Institut Straumann AG, Basel, Switzerland). The implants were aligned to be as parallel as possible to each other in mesio-distal and bucco-oral direction. Both flapless or open flap approaches were performed. Two reduced-diameter titanium-zirconium implants (Roxolid®, 3.3 mm diameter, Institut Straumann AG, Basel, Switzerland) were inserted using guided surgery (coDiagnostiX, Dental Wings GmbH, Freiburg, Germany). All implants were inserted with nonstandardized interabutment distance. Guided bone regeneration was allowed in case of small buccal dehiscence or fenestration defects. Therefore, autologous bone from the surrounding as well as a xenograft material (Bio-Oss®, Geistlich Pharma AG, Wolhusen, Switzerland) was used in combination with a collagen membrane

(Bio-Gide®, Geistlich Pharma AG, Wolhusen, Switzerland).

Prosthodontic procedure

Following the healing period of 2 months for transmucosal and 4 months for submucosal healing, implant impressions were performed using the perforated maxillary denture as impression tray. Impression posts were shortened to execute the impression in full occlusion. In this way the intermaxillary relation was simultaneously registered (Batenburg et al. 1993). The dental technician modified the maxillary dentures to implant overdentures (IODs) with incorporated chromium-cobalt framework (Vitallium® 2000, Dentsply, York, United States) and full palatal coverage. The patients wore provisional dentures during this time. Two titanium matrices were indirectly fixed to the overdenture base. At the day of insertion, the retentive anchors (Retentive anchor abutment, Institut Straumann AG, Basel, Switzerland) were fitted to the implants with a defined torque. A balanced occlusion without anterior contacts in habitual occlusion was achieved. The patients were instructed on proper overdenture handling and oral hygiene measures. The IODs were worn for 2 months. Thereafter, the dental technician reduced the palatal coverage until the metal frame in all patients and the altered maxillary IODs were worn for another 2 months. The influence of the palatal coverage on patient satisfaction was assessed in another study (Zembic et al. 2015). Subsequently, each patient selected the overdenture design of preference. Seventeen patients chose to continue wearing the IOD with reduced palatal coverage. In 4 patients IODs were sent for translation to full palatal coverage to the in-house dental lab.

Clinical evaluation

Implants and overdentures were controlled at 4 years following insertion of maxillary IODs, i.e. implant loading. Implant survival was assessed. Standardized single radiographs were made to evaluate bone levels and measure peri-implant bone level changes to baseline. The peri-implant mucosa was checked for overgrowth or any sign of inflammation. Overdentures were checked for sufficient retention, the need for rebasing, fractures and abnormal wear (heavily abraded denture teeth). The occlusion was controlled and if needed adjusted to be balanced. The matrices were inspected to be firm and complete. In case of mobility, matrices were tightened or directly re-inserted to the overdenture base using acrylic. In case of fractures of

matrix or metal spring, new components were inserted. Any biological, technical and adverse event was noted.

Statistical analysis

At the 4-year follow-up the bone levels were compared to baseline by means of the clustered Wilcoxon signed-rank test (considering 2 implants per patient). Implant survival was assessed by means of Kaplan Meier. The statistical significance was set at $p \leq 0.5$. The Wilcoxon signed-rank test was calculated with the software R (Team 2015). All other events were presented in a descriptive way.

Results

Fourteen patients (5 women, 9 men) with 26 implants were available at a mean follow-up of 4 years (range 3.6 – 4.2 years). Three patients (1 woman, 2 men) could not attend the follow-up visit. One patient dropped out of the study because he received a new overdenture from his private dentist. Three patients were not willing to participate in the study any longer and withdrew from it.

There were 5 implant failures in 4 patients (1 woman, 3 men). The Kaplan Meier implant survival rate resulted in 75%. One patient lost both implants subsequently prior to the 4-year control. This patient was a smoker. Considering the other patients with implant loss, 2 patients were non-smokers (1 woman, 1 man) and 2 patients were smokers (both men). One patient showed abnormal wear of overdenture teeth within 7 months following overdenture insertion indicating parafunctions (Fig. 1a,b). In all of the patients with implant failures the implants were placed without GBR procedures and with a flapless approach. Implant loading was performed at 3 months.

In the opposing jaw, 3 patients were wearing implant overdentures on 2 mandibular implants and a bar and 1 patient had a clasp-retained denture on 3 abutments (teeth).

There was significant marginal bone loss at 4 years compared to baseline, $p<0.001$ (mean mesial 0.9 mm, SD 1.5 mm; mean distal 1.0 mm, SD 1.3 mm; median mesial 0,8 mm, median distal 0.6 mm; IQR mesial 1.7 mm, distal 1.3 mm).

Mucositis was detected around 1 implant in a patient, where an excision of mucosa overgrowth was needed in the first year (Fig. 2). No other biological complications were evident at 4 years (Fig. 3).

With regard to the overdentures, 2 indirect rebasings were needed in 2 patients.

There were 3 fractures of overdenture teeth in 2 patients and overdentures were sent to the lab for repair (Fig. 4).

From 1 year until 4 years, there were 17 matrices mobile in 10 patients (9 men, 1 woman). Out of these, 5 matrices were mobile twice within the observation period (in 4 male patients). Seven matrices were mobile only once in 7 patients (6 men, 1 woman). In one patient the matrix on one side was mobile twice and the contralateral matrix was mobile once. In total, 20 metal springs of the matrices were lost and 10 were broken in 7 patients (2 women, 5 men) and had to be replaced. In most patients (5/7) the same site was affected several times (up to 6 times). One patient lost 1 complete matrix, which had to be replaced.

Discussion

The present study revealed a cumulative 4-year implant survival rate of 75%. There was significant peri-implant bone loss from baseline to 4 years. The incidence of technical complications was high during the observation period in terms of loss of retention, mostly (broken metal springs, mobile matrices).

A recent study reported a similar implant survival rate of 76.8% at 10 years for 3 splinted and unsplinted implants in the maxilla retaining an overdenture (Ma et al. 2016). Interestingly 94% implant failures (15/16) occurred until the 1-year follow-up. The patients wore overdentures on 2 implants in the mandible.

Splinting of implants did not show a positive effect on implant survival rates or peri-implant bone loss both for mandibular and maxillary overdentures (Bergendal & Engquist 1998; Gotfredsen & Holm 2000; Naert et al. 2004; Smedberg et al. 1999).

As observed in the study above, implant loss is most frequently seen within the first year, while less than 50% of implants fail to a later timepoint (Esposito et al. 1998).

There is no conclusive answer to the question of whether the prosthetic status in the opposing jaw is of importance for the implant failure rate and/or peri-implant bone loss (Carlsson et al. 2000). It was found that the chewing muscle increases in thickness following treatment with a mandibular IOD on the other hand (Muller et al. 2013). To keep the chewing forces low and reduce the risk of complications, care was taken in the present study to include not more than 4 abutments in the mandible. Still, a high number of implants failed.

In general, implant survival rates are higher in the mandible compared to the maxilla when retaining or supporting overdentures (Engquist et al. 1988; Hutton et al. 1995; Quirynen et al. 1992). This might be due to the almost two times higher mandibular bone density (Kim & Henkin 2015). In addition, there is a difference in the biomechanical behaviour of maxilla and mandible. During function, there is a deformation of the mandible in contrast to the rigid maxilla (Goodkind & Heringlake 1973). As a consequence, the maxilla lacks a shock-absorbing effect and may not tolerate applied forces in the same way (Rodriguez et al. 2000). Unfavorable loads to the implants might have contributed to low implant survival rates and increased peri-implant bone loss in the present study. A possible relation of a small number of implants and a high implant failure rate in the maxilla has previously been discussed (Chan et al. 1998). It has to be considered that implant loss in case of 2 implants puts the remaining implant at higher risk for failure in comparison to a higher number of

implants. Even though, only 1 patient lost both implants in the present study. Consequently, one might expect more imlant failures with longer follow-up.

Lower implant survival rates in the maxilla were associated with an implant number of less than 4 as compared to 4 implants (estimated 5-year implant survival rate of 70% vs. 89%) (Kern et al. 2016). Thereby the risk of implant loss was 3 times increased for overdentures retained by less than 4 implants. These results are in accordance with other studies including the present one. The survival rate was 86% for 2 implants supporting a maxillary overdenture at a mean loading time of 7 years (12 patients, 8 with ball, 4 with bar) compared to 99% for 4-6 implants (32 patients with bar) (Sanna et al. 2009). Interestingly, patient satisfaction was still high with maxillary overdentures on 2 implants (Zembic & Wismeijer 2013). Generally, there is a preference of patients towards minimally invasive treatment options with dental implants (Hof et al. 2014). The main reasons for patients to refuse implant surgery are fear of surgical risks and costs (Ellis et al. 2011; Walton & MacEntee 2005; Zitzmann et al. 2007). Thus, less invasive implant treatment options are needed to offer edentulous patients more alternatives for an enhanced prosthesis retention, function and well-being.

The implant surface was found to influence the outcomes in the edentulous maxilla, whereas the implant system and implant length did not show any effect (Jokstad et al. 2016). Moderately rough surface implants are nowadays considered the ideal surface with regard to osseointegration and bone to implant contact. With regard to the implant material, titanium alloy containing zirconium showed superior mechanical strength compared to grade 4 titanium (Ho et al. 2008). There were no significant differences of clinical parameters, bone levels and survival rates of titanium zirconium implants compared to grade 4 titanium implants in the mandible retaining overdentures at 5 years (Muller et al. 2015).

A higher incidence of mechanical complications was found for maxillary implant overdentures compared to mandibular ones, especially without palatal coverage (Andreiotelli et al. 2010; Sadowsky 1997; Widbom et al. 2005). Since the overdenture on 2 implants is primarily mucosa worn and only implant-retained, pronounced forces are likely to be transmitted to implants and components. In contrast, implant-supported overdentures on 4 and more implants transmit fewer forces to the implants and allow for less movement of the overdenture (Zou et al. 2013). On the other hand, one might consider a fixed reconstruction, when the bone conditions allow for the

placement of a higher number of implants without bone grafting procedures. It is well known that the incidence of prosthetic complications is much higher (4-10 times) for removable prostheses on implants compared to fixed prostheses on implants (Berglundh et al. 2002). However, a fixed reconstruction would not haven been an option in the study patients being edentulous for a long time and adapted to conventional dentures.

It was reported that implants not being placed in a parallel way might cause technical complications (van Kampen et al. 2003). Furthermore, implant angulation may compromise the retention of solitary abutments (Gulizio et al. 2005). In the present study, care was taken to plan the implants as parallel as possible using a parallelization feature of the digital planning software. Even though, loss of retention due to broken metal springs of the matrix was a common problem. Loosening or fracture of prosthetic components, regardless of the anchoring system, is a common phenomenon implying the need for changes of the retention system (Sadowsky 2007). The relatively high number of complications within the short observation period in this study is in agreement with the literature (Chan et al. 1998; Ekfeldt et al. 1997; Jemt et al. 1992; Widbom et al. 2005). It was reported that the highest frequency of complications occurs in the first year (Trakas et al. 2006; Walton & MacEntee 1994; Zarb & Schmitt 1996). In the present study, complications occurred several times on the same site, which indicates pronounced wear. Despite a huge amount of metal spring replacements, the handling of ball attachments and matrices was easy and advantageous over a splinted retention system, like e.g. a bar. Ball attachments require less space within the overdenture, are easy to clean and are low in cost (Watson et al. 2001).

In the present study, a cast framework was fabricated for each overdenture, which prevented major fractures. There were only minor fractures of overdenture teeth, which could be easily repaired. There is evidence showing a 3 times higher fracture incidence for the maxilla than for the mandible (Watson et al. 1997).

Conclusions

Two implants in the maxilla as overdenture retention might serve as minimal invasive alternative to conventional dentures in complex cases, like e.g. pronounced alveolar bone resorption and medically compromised or geriatric patients. When applying this treatment concept, the clinician should consider different and significantly lower implant survival rates than for partially edentulous patients (Jung et al. 2012; Pjetursson et al. 2012). In addition, a high amount of maintenance and technical complications should be accounted for when retaining overdentures on 2 maxillary implants in edentulous patients. As a result, a frequent and strict maintenance program might be advisable. Whether a complete palatal coverage of the overdenture would have contributed to a more advantageous load distribution and thereby higher implant survival rates remains to be answered.

Acknowledgements

This study was partly funded by the Academic Center for Dentistry Amsterdam (ACTA), The Netherlands. Implant materials were supplied free of charge by Institut Straumann AG, Basel, Switzerland.

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Figure 1a: Pronounced overdenture tooth wear in a patient indicating parafunctions.

Figure 1b: Situation before, i.e. at the day of overdenture insertion, and after, i.e. after 7 months. The patient was a smoker and lost implant 23 at 1 year.

Figure 2: Peri-implant mucositis in a patient who needed excision of the mucosal overgrowth in the first year.

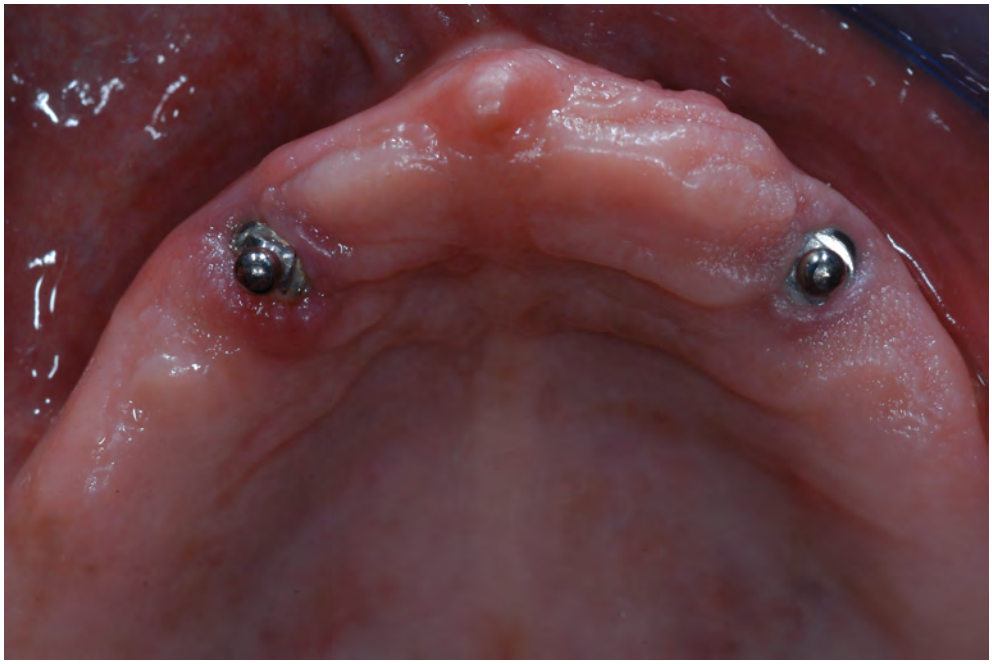

Figure 3 a-d: Four patient cases at the 4-year follow-up with visible impression of the overdenture with reduced palatal coverage.

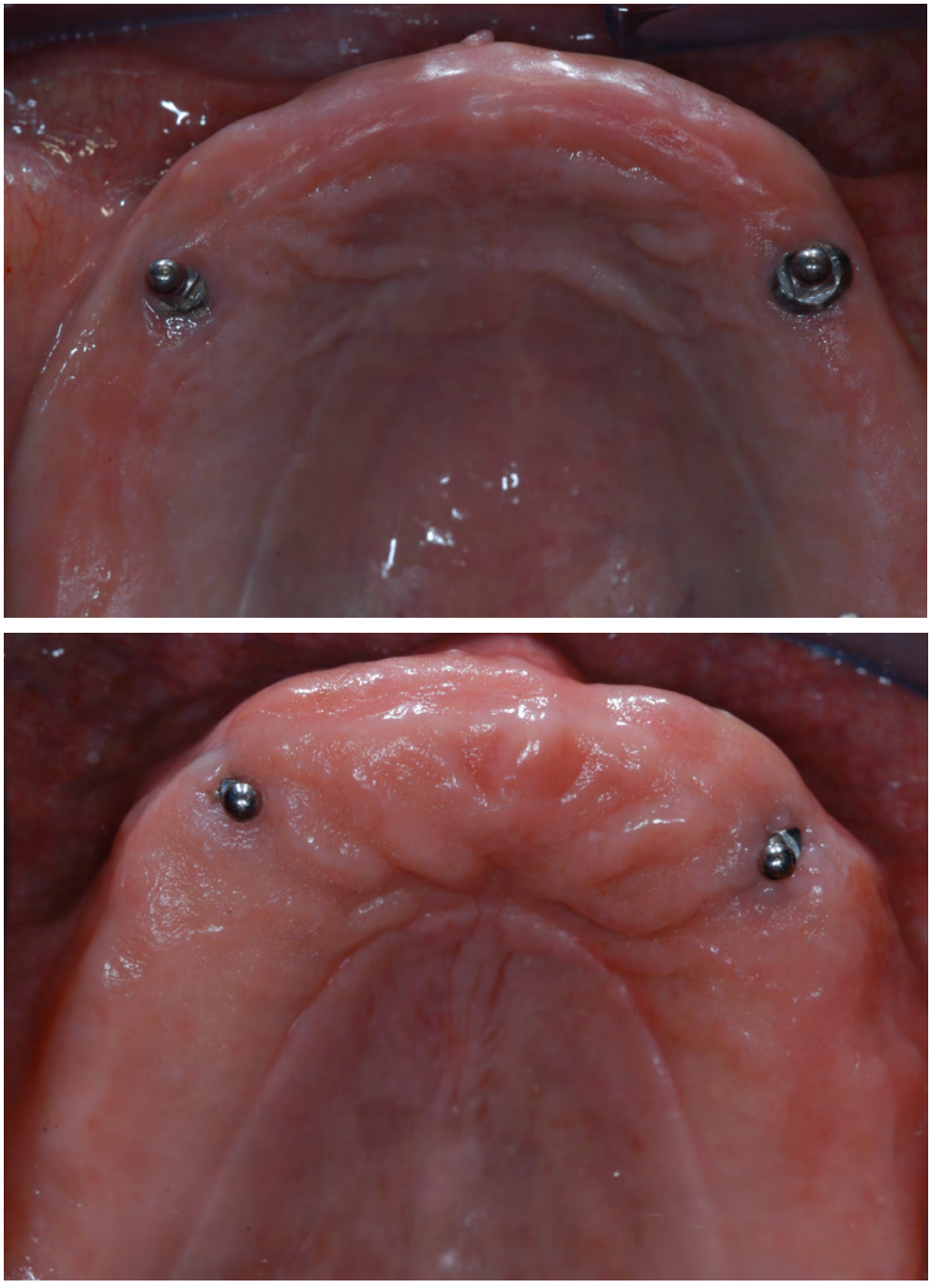

Figure 4: Several fractures of overdenture teeth in a patient with no evident parafunctions.

8

Summary

8 Summary

Even though implant-retained overdentures are a proven method of treatment for edentulous patients, based on the available evidence, no preferred treatment concept can be defined for the edentulous maxilla. In general, patients more often encounter problems with mandibular dentures compared to maxillary dentures, possibly due to the morphology and more advantageous denture bearing area of the maxilla. The rate of residual ridge resorption was found to be almost twice more
pronounced in the edentulous mandible than in the maxilla after wearing dentures for 5 years (Kovacic et al. 2010). The less pronounced maxillary ridge resorption was discussed to be due to the palate serving as resistance to forces being transmitted through the denture to the denture bearing area (Tallgren 1972). When patients start to experience problems with their maxillary dentures in terms of insufficient stability and retention, there usually is pronounced alveolar ridge resorption. Hence, the only way to enhance function and quality of life for these patients is by means of dental implants.
The improvement of masticatory function of patients with mandibular implant overdentures resulted in 1.5 – 3.6 times fewer chewing strokes as compared to patients with conventional dentures (Geertman et al. 1994).
In the posterior maxilla, placing implants usually is hindered due to an insufficient bone quantity and the need for complex bone grafting, which would impair the patient`s morbidity. Overall, there is a low prevalence of dental implants (2- 4%) with the main refusal reasons to implant surgery being fear of surgical risks and costs (Ellis et al. 2011; Walton & MacEntee 2005; Zitzmann et al. 2007). Consequently, placing implants in the anterior maxilla without extensive grafting procedures as well as less invasive implant treatment methods are needed to offer edentulous patients more alternatives for enhanced prosthesis retention, function and well-being.
From a recent systematic review on removable and fixed implant-supported prostheses in edentulous jaws it was concluded that more research should be performed on less than 4 implants in the maxilla (Kern et al. 2016). In addition, the authors stated the necessity for more clinical studies focusing on patients` benefits with respect to quality of life, psychological aspects and financial considerations (Kern et al. 2016).

Therefore, the general aim of this PhD research was to assess both the clinical performance of maxillary implant overdentures retained by 2 implants in edentulous

patients and the patient satisfaction up to 4 years after treatment.

In chapter 3 of this thesis, a within-subject prospective clinical trial is described, comparing maxillary conventional dentures and implant overdentures. Twenty-one edentulous patients encountering problems with their existing maxillary dentures were included. First, patient satisfaction of the existing dentures was assessed by means of the Oral Health Impact Profile (OHIP-20E) questionnaire and additional questions on cleaning ability, general satisfaction, speech, comfort, esthetics, stability, and chewing ability. Then the existing dentures were evaluated on quality and function and corrected in 9 patients, whereas in 12 patients' new dentures were indicated and provided. The new dentures following an adaptation period of 2 months were evaluated by filling in the same questionnaires as above. Thereafter, all patients received two implants in the canine area of the maxilla and two ball anchors retaining the overdentures. Again, patient satisfaction was determined 2 months following insertion of the implant overdentures. There was a significant improvement of patient satisfaction with implant overdentures for all domains compared to old conventional dentures ($P < 0.05$).

The fabrication of new conventional dentures improved patient satisfaction for certain parameters (physical pain, psychological disability, handicap, cleaning ability, comfort and esthetics). Consequently, only the aspects functional limitation, psychological discomfort, physical and social disability, general satisfaction, speech, stability and chewing ability were statistically superior for implant overdentures in comparison ($P < 0.05$). From this study, it was concluded that maxillary overdentures retained by 2 implants and ball anchors significantly ameliorated the quality of life of edentulous patients in the short-term.

The retention of an overdenture is an essential criterion for a patient to be satisfied and feel comfortable when speaking and functioning. Interestingly, the coverage of the tuberosities seems to play a more important role for retention than the coverage of the palate (Orstavik & Floystrand 1984). A study on maxillary overdentures retained by 4 splinted implants did not find a significant impact on patient satisfaction if overdentures were with or without palatal coverage (de Albuquerque Junior et al. 2000).

Whether reducing the palatal coverage in overdentures retained by only 2 unsplinted implants would influence patient satisfaction was addressed in chapter 4 of this thesis. The same patient group as in chapter 3 received overdentures with palatal coverage for 2 months, which were retained by 2 implants and ball anchors. Thereafter, patients filled

in OHIP-20E questionnaires and the additional issues cleaning ability, general satisfaction, speech, comfort, esthetics, stability, and chewing ability were inquired. Subsequently, the palatal coverage was reduced by the technician to the limits of the metal frame and overdentures were polished. The patients wore these overdentures for another 2 months before answering the same questionnaires. The comparison of the 2 overdenture designs yielded equal patient satisfaction for all OHIP domains. Patients were significantly more satisfied with esthetics and taste ($P < .01$) for overdentures with reduced palatal coverage. In conclusion, palatal coverage of maxillary overdentures on 2 implants did not affect patient satisfaction. It is hence worthwhile to consider the reduction of the palatal coverage in individual patients for a beneficial perception of esthetics, taste, phonetics and gag reflex.

Numerous systematic reviews investigated the question of how many implants are optimal to retain a maxillary overdenture (Gallucci et al. 2009; Kern et al. 2016; Klemetti 2008; Roccuzzo et al. 2012; Sadowsky 2007; Slot et al. 2010). Due to insufficient and weak evidence, no explicit statement could be drawn.

From the clinician`s perspective, survival of implants and prostheses, marginal bone levels and biological and technical complications are crucial for the success of a therapy. It is well known, that implant loss occurs most frequently within the first year, as so-called early failures, i.e. before implant osseointegration (Esposito et al. 1998). In contrast, less than 50% are late failures, i.e. implant loss after an established but not preserved osseointegration. For this reason, chapter 5 investigated implant survival rates, bone loss and biological and technical complications of 2 maxillary implants retaining overdentures at 1 year. The new or adjusted dentures served as templates both for the execution of a cone-beam computed tomography (CBCT) scan (NewTom 5G, QR, Verona, Italy) and for the fabrication of a surgical guide. For this reason, denture duplicates with barium sulfate were made, which were modified according to the digital implant planning (coDiagnostiX, Dental Wings Inc. Montreal, Canada). The implants were, if possible, placed in canine position. Minor guided

bone regeneration not compromising implant stability was allowed. Two diameter reduced titanium-zirconia implants were inserted to preserve as much autologous bone around the implant (Roxolid® Tissue Level, 3.3 mm diameter, Regular Neck, Institut Straumann AG, Basel, Switzerland). Since implant healing mode (trans- or submucosal) is not impairing implant survival, both modes were allowed in the present study (Astrand et al. 2002; Ericsson et al. 1997). After 3 and 5 months of healing (depending on whether

bone grafting was performed or not), ball anchors were mounted, and implant overdentures were delivered. Follow-up visits were executed at 1, 2, 4, and 8 weeks following implant insertion and 2, 4, and 12 months following overdenture insertion (baseline). Intraoral radiographs were taken at implant loading and 1 year in a standardized way with individually designed holders.

At a mean follow-up of 1.1 years (range 1.0-1.7 years), nineteen patients (1 dropout) with 38 implants were evaluated. The implant survival rate amounted to 97.3% with 1 implant lost. There was significant bone loss at 1 year (mean 0.7 mm, SD = 1.1 mm; median: 0.48 mm, IQR = 0.56 mm). More than 2 mm bone resorption was apparent around 8% of the implants. Overall 13 soft tissue events occurred during the observation period: mucosa overgrowth around 11 implants (29%) in 8 patients, 1 pain spot and 1 recession. Technical events comprised 4 minor and 2 major overdenture tooth fractures and 6 rebasings. Despite a large number of events and increased bone loss, the 1-year implant survival rate was high. On the basis of these results, 2 maxillary implants as retention for overdentures cannot be recommended as routine procedure until longer follow-up and more studies on this topic are available. Never the less, this treatment might be a suitable minimally invasive alternative for selected patient cases.

An important issue was considered in the present thesis, namely the pre-treatment assessment of patient satisfaction, which has a significant impact on the post- treatment assessment. The included patients rated their upper dentures before receiving implant therapy. An evidence-based review on PROMs in implant research concluded that many studies present only post-treatment assessments and thereby the benefit of a treatment cannot be evidenced (McGrath et al. 2012). Retrospective assessment reveals more about the recovery from an event, especially if reported with short follow-up and has the limitation of a recall bias effect (Locker et al. 2004). It was therefore recommended to assess PROMs with a follow-up of a year or longer (McGrath et al. 2012).

In chapter 6 the progression of patient satisfaction was compared from baseline to 1 and 4 years and, whether the initial benefit of the implant treatment would persist over time.

Following the evaluation of the palatal coverage (chapter 4), the patients could choose which design they favored. Two thirds (16 patients) chose for a reduced palatal coverage, while one third (5 patients) asked for palatal closure.

At 4 years, patients rated social disability the best and functional limitation the worst. Patient satisfaction did not change significantly for not any OHIP domain at 1 and 4 years compared to baseline, thus the benefit of maxillary overdentures retained by 2 implants

remained unchanged.

To be able to propose the minimum of 2 implants for maxillary edentulous patients, the clinical performance of this treatment has to be evaluated over a few years. Chapter 7 thus examined implant survival, peri-implant bone loss and incidence of biological and technical events at 4 years. Fifteen patients (10 men, 5 women) were available for a mean follow-up of 4 years (range 3.6 – 4.2 years). There were 6 implant failures in 5 patients (3 men, 2 women). One patient lost both implants subsequently. The Kaplan Meier implant survival rate resulted in 75%. There was significant marginal bone loss at 4 years compared to baseline (mean mesial 0.9 mm, SD 1.5 mm; mean distal 1.0 mm, SD 1.3 mm; median mesial 0.8 mm, median distal 0.6 mm; IQR mesial 1.7 mm, distal 1.3 mm). Mucositis was detected around one implant. No other biological complications were evident at 4 years.

With regard to technical complications occurring from 1 year until the last follow-up of 4 years, 17 matrices were mobile in 10 patients (9 men, 1 woman). In total, 30 metal springs of the matrices were lost or broken in 7 patients and had to be replaced. One complete matrix was lost in 1 patient and was renewed.

Three fractures of overdenture teeth were detected in 2 patients and 2 rebasings were needed in 2 patients. For this reason, overdentures were sent to the lab.

9

General discussion

9 General discussion

Study design

For the present thesis, a within-subject comparison was chosen as study design. This design offers the advantage of the patient being its own control, which reduces the number of patients and lessens the risk of error in variation with individual differences. A randomized controlled clinical trial (RCT) would have been the preferred choice for the authors due to the higher scientific evidence but could not be realized out of two reasons. First, due to the difficulty of defining an adequate and fair control group, considering the unclear evidence about the standard procedure for the edentulous maxilla. Second, it was discussed to set up an observational study on this new kind of treatment first and await the results. In case of successful outcomes, more studies with different kinds of control groups would be justifiable. Otherwise, patients could have felt being treated unfairly, if they would have received the option with inferior results. It was concluded that future research should be in form of well- designed observational studies complying with the STROBE statements (strengthening the reporting of observational studies in epidemiology), because RCTs have limited applicability (Rohlin et al. 2012).

It was recommended to use reliable and valid questionnaires for measurement of chewing ability in patients with oral implants, which was accomplished by means of OHIP in the present research (Feine et al. 2006).

Number of implants/ Treatment concept for the edentulous maxilla

A reduced number of implants offers several economic and surgical benefits for the patient and a higher number of implants may not necessarily lead to superior outcomes (Dudley 2013). On the other hand, according to the results of this thesis, 2 implants in the maxilla did not prove to be a reliable treatment concept as it is in the mandible. This finding might be attributed to the inferior bone quality in the maxilla compared to the mandible. Implant survival rates are in general lower in the maxilla than in the mandible when retaining or supporting overdentures (Engquist et al. 1988; Hutton et al. 1995; Quirynen et al. 1992).

Secondly, there is a difference in the biomechanical behavior of maxilla and mandible.

During function, there is a deformation of the mandible in contrast to the rigid maxilla (Goodkind & Heringlake 1973). In case of 2 anterior implants in the maxilla, the overdenture is mainly mucosa supported with a great variance of mucosal compressibility. As a result, the overdenture sinks into the soft tissues in the posterior, while there is hardly any compressibility in the implant area, resulting in significant loads being transferred to the implant. Furthermore, there is a quite large lever arm (approximately 16 mm) from the masticatory center to the canine area. Early studies have demonstrated that the soft tissue compressibility in saddle areas of partial prostheses is up to 10 times higher than physiologic tooth intrusion (Morris 1966). This effect might put implant overdentures at higher risk as compared to tooth- retained partial dentures, which could be demonstrated in the following study. When overdentures retained by 2 implants and telescopic crowns in canine position were compared to dentures retained by 2 telescopic crowns on teeth in canine area, the cumulative survival rate was only 49% for implant overdentures in contrast to 100% for tooth-retained dentures at 2 years (Weng & Richter 2007).

Considerable bending loads might negatively affect implants and the peri-implant bone and lead to implant failure. Even though it could not be confirmed that splinting of implants with a bar had a significant influence on implant survival in contrast to ball anchors for both mandibular and maxillary overdentures, splinting might be advantageous in the situation of only 2 implants in the maxilla (Bergendal & Engquist 1998). On the other hand, a bar would inevitably increase the costs and its indication depends on ridge shape and available vertical height. There was no difference for implant success when 3 maxillary implants were inserted and splinted (bar) or not (ball attachments) (Ma et al. 2016). The main reason to place implants in canine area in the present research was a more advantageous rotation axis during function. Occlusal loading causes rotation and disruption of the peripheral seal of the overdenture anteriorly, which could be prevented in the present research by the retention through implants, while incisal loading produces rotation and loss of peripheral seal of the overdenture posteriorly, which was reduced by a meticulous embracement of the tuberositas (Nelson & von Gonten 1994). Another argument to place implants in canine area in the present study were better bone conditions in the anterior than posterior maxilla. In fact, more sites showed type 4 bone quality in the posterior of the edentulous maxilla (38%) than in the anterior (7%) (Ma et al. 2016). Furthermore, a retrospective study supports the need for bone augmentation procedures in maxillary posterior regions of most edentulous

patients when placing implants (Pramstraller et al. 2011). The cumulative implant survival rate in the present thesis was 75% at 4 years and hence is rather low. One of 5 patients with implant failures lost both implants subsequently. It has to be considered that implant loss in case of 2 implants puts the remaining implant at higher risk for failure in comparison to a higher number of implants. One might expect more failures with longer follow-up accordingly.

Lower implant survival rates in the maxilla were associated with an implant number of less than 4 as compared to 4 implants (estimated 5-year implant survival rate of 70% vs. 89%) (Kern et al. 2016). Thereby the risk of implant loss was 3 times increased for overdentures retained by less than 4 implants. These results are in accordance with other studies. The survival rate was 86% for 2 implants supporting a maxillary overdenture at a mean loading time of 7 years (12 patients, 8 with ball, 4 with bar) compared to 99% for 4-6 implants (32 patients with bar) (Sanna et al. 2009). Furthermore, another systematic review reported 1-year survival rates of 89% for implants and 99% for overdentures (ball, locator, telescopic crown) in case of ≤ 4 unsplinted maxillary implants (Raghoebar et al. 2014). In case of ≤ 4 maxillary implants being splinted (bar), implant and overdenture survival increased to 97% (Raghoebar et al. 2014). These results are in disagreement with the already reported findings that splinting of implants did not have a significant effect on implant survival (Bergendal & Engquist 1998; Ma et al. 2016). The reported findings base on machined implant surfaces in one study, while in the other study 3 implants in the maxilla were randomly allocated to being either splinted or not. The implant survival rate amounted to 86% at 10 years for 3 tripodal narrow diameter implants in the maxilla retaining overdentures with reduced palatal coverage, which is a quite reasonable result (Ma et al. 2016). More studies are needed to evaluate the impact of splinting in the maxilla with a small number of implants (≤ 4) and recent moderately rough implant surfaces.

In general, the survival rates for maxillary overdentures are inferior to maxillary fixed prostheses (estimated 5-year implant survival rate of 89% vs. 99%) (Kern et al. 2016). Implant loss was found in 2-3% supporting fixed reconstructions, while more than 5% of implants failed in overdenture therapy at 5 years (Berglundh et al. 2002). The incidence for implant loss was found to be highest in removable prostheses compared to other types of implant prostheses also in another study (Goodacre et al. 2003). It is generally accepted that removable prostheses are the preferred treatment option for the

elderly. Considering the increasing life expectancy today, patients are likely to become edentulous at an older age. As a consequence, patients might have a compromised general health and reduced dexterity. It was found that oral bacteria correlate with the occurrence of systemic and cardiovascular diseases, endocarditis and pneumonia through bacteremia (Ford et al. 2007; Iwai 2009; Kim & Amar 2006; Rautemaa et al. 2007; Scannapieco et al. 2003). Overdentures that are easy in handling and cleaning should therefore be the treatment of choice in elderly edentulous patients. It was assumed that the number of implants does not affect peri- implant health (Batenburg et al. 1998). Furthermore, recent evidence demonstrated that the peri-implant soft tissue health seems not to be influenced by the attachment type (either ball or bar) (Trakas et al. 2006). Even though, there is a tendency for more hyperplasia with bar attachments, especially when the oral hygiene is inadequate. In addition, it is a common observation that there is mucosal growth underneath maxillary overdentures (Trakas et al. 2006). In the present research, mucosa overgrowth was a common problem appearing around ball attachments in 30% of the patients. Thereby, the predefined height of the ball attachments of 3.4mm impeded the handling of mucosa overgrowth, despite several attempts to surgically remove the hyperplastic tissues. This resulted in pain for some patients when inserting the overdentures and could have tempted them to remove the overdentures infrequently. Whether this had an effect on implant survival remains unclear.

Reduced-diameter implants/Titanium-zirconia implants

Horizontal bone resorption is common mesial to the maxillary sinus and impedes implant placement (Cawood & Howell 1988). Considering the suggested 1.5mm of residual bone that should be present on the buccal and palatal side following implant placement, the insertion of a regular diameter implant of 4mm is hindered. For economic reasons and to avoid bone grafting, a suitable alternative is the use of diameter reduced implants corresponding to a diameter of less than 3.5mm.

On the other hand, there is a risk of fatigue fracture for titanium implants with narrow diameter being exposed to high loads or in function for a long time (Weng & Richter 2007; Zinsli et al. 2004). The strength of narrow diameter titanium implants could notably be increased by advancements of material science. In contrast to previous grade 4 titanium, a titanium-zirconia alloy (83-87% titanium, 13-17% zirconia) was developed as implant material, which showed higher tensile and fatigue strength (Ho et al. 2008).

In this way, the diameter of 4mm could be reduced to 3.3mm with the same indication area as the former.

Unfortunately, there are very few studies on narrow implants and edentulous maxilla. A study concluded that 3 narrow diameter implants can be used for the edentulous maxilla to retain overdentures, even though the 1-year implant survival rate was only 85% (Payne et al. 2004). A retrospective case series on 4 titanium-zirconia implants and locators as overdenture support in the edentulous maxilla, reported an implant survival rate of 100% at 12-16 months of follow-up (Cordaro et al. 2013). These results have to be interpreted with caution, since data was achieved by reviewing patient charts and only 10 patients were included.

For the edentulous mandible, no significant difference was found for the cumulative survival rate of 3.3mm titanium-zirconia implants (99%) compared to 3.3mm grade 4 titanium implants (98%) as overdenture retention at 5 years (Muller et al. 2015).

Patient satisfaction

A significant increase in patient satisfaction can be observed when dentures are renewed, which is in agreement with the results of this thesis (Allen et al. 2006; Ellis et al. 2007). The comparison of the perception before and after a treatment is of influence for the patient`s evaluation of the treatment. Patients being dissatisfied with their conventional dentures are likely to be more satisfied with maxillary implant overdentures than those with no complaints (Andreiotelli et al. 2010; Zitzmann & Marinello 2000). Unfortunately, it is often not reported whether the patients were dissatisfied with their previous dentures. Missing OHIP measurements before the treatment were discussed to be a drawback in a study on maxillary overdentures retained by 3 implants without palatal coverage (Mo et al. 2016). In the present research, a criterion for inclusion was, that patients encountered problems with their dentures. The latter were assessed with OHIP before dentures were either enhanced or remade and patients wore these enhanced/new dentures for 5-7 months until implant-retained overdentures were inserted. Following the recommended adaptation period, patients judged implant overdentures by means of OHIP another 2 months later. This time period was most likely beneficial to wash out a possible effect of the initial dissatisfaction on the appraisal of implant overdentures. In addition, the dentures served as master for the implant overdentures, which did not differ in terms of shape and the effect of the implants could thereby be evaluated in an optimal way. It was suggested that a baseline assessment of satisfaction towards a treatment

should be related to the assessment of the pre-treatment satisfaction, which was achieved in the present thesis (Wiklund 2004).

Psychological and neurophysiological aspects allow for acceptance of rehabilitation with a new removable appliance for most patients within 2-4 weeks (Feine et al. 2006). In the present thesis, the well-known adaptability of the stomatognathic system was considered and PROMs were assessed 2 months following delivery of overdentures and their adjustments. Furthermore, an adequate denture retention facilitates adaptation, which was achieved by adjusting old dentures or making new ones (Muller et al. 1995).

In the present research, patient satisfaction was high for overdentures retained by 2 maxillary implants and ball anchors, which is in agreement with a study on overdentures retained by 3 maxillary implants and locators (Mo et al. 2016). Studies on 4 and even 6-8 maxillary splinted (bar) implants retaining overdentures also reported high levels of patient satisfaction (de Albuquerque Junior et al. 2000; Naert et al. 2004; Naert et al. 1998; Zitzmann & Marinello 2000). According to the evidence of 2 systematic reviews, patient satisfaction on maxillary implant overdentures seems to be independent of both number of implants and attachment type (De Bruyn et al. 2015; Klemetti 2008). The period of edentulism is probably more decisive. Patients who have been edentulous for a longer period tend to be more satisfied with an implant overdenture as opposed to patients being edentulous only recently (De Bruyn et al. 2015). The patients in the present thesis were all edentulous for more than 1 year and well adapted to dentures, which might explain the high levels of patient satisfaction.
Patients profited most with regard to an enhanced social disability, which is likely to be attributed to superior overdenture retention through the implants. There were no differences in retention and stability of maxillary overdentures for patients receiving 5-6 implants as compared to those receiving only 2 implants (Kuoppala & Raustia 2015). It has to be considered though, that only 2 patients received 2 maxillary implants, while 8 patients received 5 and more implants in that retrospective study. An unstable overdenture has a huge impact on the self-confidence of a person and thereby negatively affects the social life (Wismeijer et al. 1997). People tend to retract from social events due to feelings of uncertainty and discomfort. On the other hand, patients were satisfied least with functional limitation at baseline, 1 and 4 years. Thus, the ability to chew seems restricted with a minimum of 2 implants. Surprisingly, functional limitation at 4 years was

not significantly altered with full versus reduced palatal coverage (OHIP score 27.3, SD 31.9 vs. OHIP score 23.9, SD 22.1) and patients tended to be more satisfied with an open palate. Opening the palate might give the patient the illusion of having own teeth and the intraoral stereognostic ability is not adversely affected (Kumamoto et al. 2010). In addition, the relevance of taste should not be underestimated, being an important aspect of function. It was concluded that the perception of flavor is adversely affected by complete dentures and the appreciation of flavors is more crucial than the identification of the taste quality (Giddon & Hittelman 1980). Furthermore, it was assumed that covering the palate might inhibit bolus formation during mastication with the result of an increased number of mastication strokes before comfortable swallowing (Sato et al. 2013). Patients were equally satisfied with (12 patients) and without (6 patients) palatal coverage of overdentures, which is in accordance to the results of the present thesis (Kuoppala & Raustia 2015). On the other hand, in situations with a reduced number of implants as overdenture retention and no palatal coverage, a higher amount of technical complications might be the consequence, such as wear of patrices and losening or fracture of matrices (Raghoebar et al. 2014; Sadowsky 2007; Slot et al. 2010). The decision of covering the palate or not should therefore be made wisely on an individual basis.

The patient`s motivation for a treatment can be independent of the denture itself and can create certain bias when assessing PROMs to rate specific treatments. Significant improvements of patient satisfaction with mandibular implant-retained overdentures were reported, when patients received their preferred treatment (Allen et al. 2001). In the present thesis, the patients profited from reduced fees for the implant treatment. This financial benefit might have created certain bias when assessing patient satisfaction with the result of a more positive evaluation of implant overdentures. On the other hand, the assessment of patient satisfaction at 4 years remained unchanged to baseline and 1 year, which stands for an unaltered satisfaction, whereas it was stated that OHIP is likely to change over time (Mo et al. 2016). There would have been a significantly reduced patient satisfaction at 4 years, if patients were influenced by an initial enthusiasm. Whether the enthusiasm can persist over a period of 4 years remains unclear, but it is assumable that the potential bias can be neglected. A systematic review on maxillary implant overdentures confirms the finding of this thesis with unchanging perception of the evaluated parameters in studies with longer follow-up (Sadowsky & Zitzmann 2016).

The authors speculate an additional adaptation to the treatment over time as reason.

Biological/technical complications

It was assumed that a greater implant failure rate for removable over fixed prostheses in the maxilla was attributed to an inadequate bone volume preoperatively (Bryant et al. 2007). As mentioned in the introduction, patients in need of implant overdentures often appear to have a compromised bone morphology. However, it is striking that also patients with excellent bone conditions lost implants in the present research. This indicates that other factors, such as e.g. biomechanics, might be of substantial influence.

Most studies on maxillary overdentures don`t report the condition of the peri-implant tissues (Raghoebar et al. 2014). In general, more complications (52%) were observed for implant-supported overdentures compared to fixed prostheses (32%), with peri-implant mucositis/ hyperplasia and retentive clip fractures being most often (Berglundh et al. 2002; Brennan et al. 2010). On the other hand, when the conditions allow to place a higher number of implants, the overdenture is mainly implant- supported and one might choose for a fixed reconstruction as alternative. Insertion of only 2 implants in the maxilla cannot be compared to a fixed reconstruction. The overdenture is implant-retained, and mucosa worn and sinks in the posterior during function. Compared to the mandible, there is more pronounced soft tissue resilience in the maxilla. The increased freedom of movement for the overdenture might explain the high amount of rebasings within a short period in the present thesis. Furthermore, the smaller the number of implants, the more relevant are soft tissue resilience and morphology of the area being covered by an overdenture, i.e. the palate, vestibulum and tuberositas in the maxilla. Since most patients preferred a reduced palatal coverage, this might have contributed to more mobility of the overdentures and finally to the amount of complications. The high number of technical events in the present thesis is in accordance with the literature. When reviewing the evidence on splinted and unsplinted implants supporting overdentures, the need for more prosthetic maintenance was found for unsplinted implants, although there was no significant effect on peri-implant outcomes and patient preference (Stoumpis & Kohal 2011). There is a noteworthy trend that most maintenance requirements appear within the first year (Allen et al. 1997; Trakas et al. 2006; Walton & MacEntee 1997). The occurrence of technical complications is in line with another study, which reported fractures and loosening of attachments and overdenture fractures to be a common

problem with maxillary implant overdentures (Visser et al. 2009). During mastication, high forces are applied to the attachment systems and overdentures. Thus, the components must withstand high loads. The patients have to be informed that wear is a natural aging process that will appear with time. As a consequence, a regular maintenance and post-insertion care of implants and overdentures is a sine qua non. With a minimum number of implants, more events have to be taken into account. Thus, the advantages of lower costs, less treatment time and less morbidity and invasiveness of this treatment strategy have to be contrasted with the need for more maintenance and thereby more appointments with the patient. This should be calculated for when making a cost-effective treatment plan and discussing the various treatment options with the patient.

Complications are likely to have an impact on patient satisfaction, which surprisingly was not corroborated in the present thesis. On the basis of a summit on clinical practice guidelines for the edentulous maxilla it was summarized that both clinicians and patients have to accept a lifelong need for maintenance and management of biological and technical complications (Stanford 2016).

The patients` judgment of satisfaction varies not only with individual preference and expectation, but also with the manner of information through the dentist (Bradley 1993). The patients should therefore be clearly and sufficiently informed prior to implant treatment both about the procedure and the incidence of complications, which will necessitate dental appointments especially in the first year following insertion.

Peri-implant bone loss

Pronounced marginal bone loss might be a predictor to future implant loss. It is consequently important to measure bone levels in a standardized and reproducible manner. For this reason, individual lab-made x-ray holders were fabricated for each implant in the present thesis. Despite this effort to ensure an accurate analysis of bone levels, it was not always possible to replicate the x-ray in the same angle as baseline, resulting in slight deviations of the implant axis. The main challenge in positioning comprised the palate. Significant bone loss was found from baseline to 4 years, which might have influenced the present implant survival rates.

Attachment system

Considering overdenture anchorage with different attachment types, there was no significant difference for implant survival whether ball anchors (0.3 % implant loss per year) or bars (0.4% implant loss per year) were used (Kern et al. 2016).

According to the results of a previous study analyzing the effect of palatal support on various implant-retained overdenture designs, it was concluded that the removal of the palatal support resulted in a greater load transfer and more concentrated stress around the implants than the selection of the attachment system (Ochiai et al. 2004). In a study on 2 implants in canine position with telescopic crowns and no palatal coverage, 1 implant fracture and 4 implant failures (implant failure rate of 18%) were observed at 2 years of loading (Weng & Richter 2007). A reduced implant diameter was used (3.25mm). The authors discussed overload as cause for the outcomes (Weng & Richter 2007). Whether the rigid telescopic anchorage or the missing palatal support contributed to the high implant failure rate remains unclear though. Solitary attachments offer several advantages, comprising cleanability, less space requirement within the overdenture, cost-effectiveness and low technique sensitivity (Watson et al. 2001). Problems with loosening of attachments are more common with 2 implants and ball anchors and retention and stability are superior with a higher number of implants and a bar (Klemetti 2008). That is why it has been recommended that maxillary overdentures should be retained by at least 4 implants independent of the attachment system (Klemetti 2008).

Retentive forces of ball attachments range from 3 N to 85 N (Setz et al. 1998) and from 27 N to 35 N (Petropoulos & Smith 2002). An in vitro study evaluated the effect of different implant angulations on the retentive properties of ball attachments on 2 implants supporting overdentures (Al-Ghafli et al. 2009). The greatest longevity of retention was achieved when implants were angulated 0 and 5 degrees (Al-Ghafli et al. 2009). In situations with only 2 implants supporting solitary attachments, the wear of both matrix and patrix strongly depends on the parallelism of the inserted implants. To ensure implants to be as parallel to each other as possible and in canine position, preoperative diagnostics and implant planning by means of a cone beam computed tomography scan was executed in the present thesis. In this way, both the anatomical situation and the prosthetics were considered.

Occlusion

A systematic review addressing the influence of opposing teeth on the success of maxillary implant overdentures stated that antagonistic teeth might put implants at risk for failure (Ohkubo & Baek 2010). This was taken into account in the present thesis, where only patients being edentulous or having a maximum of four abutments (teeth or implants) in the mandible were included. Thus, survival of the present implants was most assumable not negatively affected by the occlusion.

10

Conclusions and future perspectives

10 Conclusions and future perspectives

Two implants in the maxilla as overdenture retention can contribute to a higher patient satisfaction and thereby quality of life for individual patients being unhappy with conventional dentures. On the other hand, the treatment approach studied in the present thesis should be implemented as minimal invasive alternative in exceptional situations. Significantly lower implant survival rates and a much higher amount of technical and biological complications have to be accepted with a minimum of 2 maxillary implants in edentulous patients compared to partially edentulous patients (Jung et al. 2012; Pjetursson et al. 2012). The high 1-year implant survival rates of 97% dropped in this research tremendously to 75% at 4 years. Thus, the clinician should restrict the use of 2 maxillary implants for overdenture retention to specific cases, e.g. pronounced bone resorption and geriatric or medically compromised patients. The results of this thesis also showed increased bone loss. It is unclear, whether the removal of the palatal coverage contributed to these results. Most patients preferred an open palate and significantly higher patient satisfaction was found with regard to esthetics and taste. Since in these patients, function is of higher priority than esthetics, one might consider keeping the palate closed not to compromise the results.

Minimal invasive treatment approaches will be needed in future in general, but particularly for geriatric edentulous patients. It was suggested that the motivation for patients to receive dental implants also late in life should be promoted through competent information and minimally invasive procedures to enhance the quality of life of these patients (Muller 2014). The magnitude of invasiveness is difficult to define in implant dentistry, since a surgical procedure is still needed. It was suggested to estimate the patient`s physical tolerance and acceptance to a long and invasive treatment before starting the therapy to lower the patient`s morbidity (Muller 2014).

Several studies have proposed that future clinical research should target patient-reported outcomes on different alternatives for maxillary implant-retained overdentures besides long-term examination of implant and overdenture survival (Listl et al. 2014). Thus, research in terms of large, well-designed prospective long- term trials on different implant numbers should be promoted to broaden the portfolio of treatment options for maxillary edentulous patients.

To date it is unknown, how implant failures or other complications during the course of a treatment affect patient satisfaction. Almost 60% of the patients were expecting implants to last for a lifetime in a study assessing patients` perspectives when receiving implant therapy (Hof et al. 2014). It would be of great benefit, if future PROMs would be assessed at 5 and 10 years following a certain treatment and in patients experiencing implant failures and other complications. All the more, since the individual`s attitude towards a treatment is not constant and changes with time due to experiences, adaptation to the reconstruction and life events (Allen 2003).

For assessment of patient satisfaction, OHIP was used in this thesis. Even though being a proven questionnaire, it would be worth a revision including factors like speech, cleaning ability, economic issues and the impact of complications.

In consensus meetings where the knowledge and experience of experts is combined with data from most recent evidence, criteria should be defined for recommended regular maintenance procedures of implant overdentures (interval, checklist of parameters to be controlled) to minimize the appearance of complications.
In addition, statements should be formulated on the regular amount of expected wear and maintenance, like e.g. activation or replacement of retentive systems and rebasings as opposed to unexpected complications, like e.g. fractures of overdentures.

Addendum

Samenvatting

Voor de edentate patiënt is een overkappingsprothese in de onderkaak op implantaten een veel toegepaste behandeling die wetenschappelijk goed onderbouwd is.
In tegenstelling tot de onderkaak is er in de bovenkaak tot op heden geen consensus in de beschikbare wetenschappelijke literatuur voor een goed concept voor een overkappingsprothese in de bovenkaak.
Over het algemeen hebben edentate patiënten meer problemen met een prothese in de onderkaak ten opzichte van de prothese in de bovenkaak. Een mogelijke verklaring hiervoor is de morfologie van de bovenkaak ten opzichte van de onderkaak en het grotere draagoppervlak van de bovenkaak.
Het resorptieproces in de onderkaak verloopt 2 keer zo snel als in de bovenkaak 5 jaar na het dragen van een volledige onder- en bovenprothese (Kovacic et al. 2010). Het minder grote resorptie patroon in de bovenkaak wordt toegeschreven aan het feit dat het palatum weerstand biedt aan de krachten die worden doorgegeven door de prothese aan het onderliggende weefsel (Tallgren 1972). Als er bij een bovenprothese problemen ontstaan in de vorm van onvoldoende stabiliteit en houvast (retentie) is dit meestal het gevolg van vergevorderde alveolaire botresorptie. Om de functie van de prothese en de kwaliteit van leven te verbeteren van deze patiënten is plaatsen van tandheelkundige implantaten de behandeling van eerste keus.
Bij patiënten met een implantaat gedragen prothese in de onderkaak verbetert de kauwfunctie, zij hebben 1.5 tot 3.6 minder kauwcycli nodig ten opzichte van patiënten met een conventionele gebitsprothese (Geertman et al. 1994).
In veel gevallen is de bothoeveelheid in het achterste gedeelte van de bovenkaak (anterieure maxilla) onvoldoende om implantaten te plaatsen. Complexe bot augmentaties zijn dan nodig wat de bezwaren na de behandeling vergroot. Over het algemeen worden er weinig implantaten in de bovenkaak geplaatst bij de edentate patiënt (2-4%) met als grootste redenen chirurgische risico's en hoge kosten (Ellis et al. 2011; Walton & MacEntee 2005; Zitzmann et al. 2007). Het plaatsen van implantaten in het voorste gedeelte van de bovenkaak (premaxilla), waar de bothoeveelheid over het algemeen groter is en waar uitgebreide botaugmentaties en dus invasieve operatietechnieken achterwege gelaten kunnen worden, is noodzakelijk om de edentate patiënt meer retentie van de bovenprothese te geven en daarmee de functie en het welbevinden te vergroten.

Uit een recent systematisch onderzoek waarbij zowel vaste als uitneembare voorzieningen op implantaten werden beoordeeld werd geconcludeerd dat er meer onderzoek gedaan moest worden naar het plaatsen van minder dan 4 implantaten in de bovenkaak voor een uitneembare voorziening (Kern et al. 2016). Daarnaast gaven deze auteurs de noodzaak aan voor meer klinisch onderzoek waarbij aandacht wordt gegeven aan de voordelen van de patiënt met aandacht voor de kwaliteit van leven, psychologische en financiële aspecten (Kern et al. 2016).

Het algemene doel van dit proefschrift was zowel het klinische aspect als de tevredenheid van de patiënt te onderzoeken van een overkappingsprothese in de bovenkaak op 2 implantaten bij de edentate patiënt over een periode van 4 jaar. In hoofdstuk 3 van dit proefschrift wordt een klinische prospectieve studie uitgevoerd waarbij de ervaring van de patiënt wordt geëvalueerd. Hierbij wordt een conventionele prothese vergeleken met overkappingsprothese op 2 implantaten in de bovenkaak. Eenentwintig edentate patiënten die problemen hadden met de bestaande boven prothese werden geïncludeerd. Als eerste werd de tevredenheid over de bestaande prothese beoordeeld aan de hand van de vragenlijst van de Oral Health Impact Profile (OHIP-20 E). Verder werden er aanvullende vragen gesteld over schoonhouden van de prothese, algemene tevredenheid, spraak, comfort, esthetiek, stabiliteit en kauwvermogen. De kwaliteit van de bestaande boven prothesen werd beoordeeld en werd bij 9 patiënten aangepast. Bij 12 patiënten was een nieuwe prothese geïndiceerd en werd een nieuwe prothese vervaardigd. Na 2 maanden gewenning werden bij deze 12 patiënten de nieuwe prothesen geëvalueerd volgens dezelfde vragenlijsten als bovengenoemd. Alle patiënten kregen 2 implantaten in de cuspidaat regio van de bovenkaak welke na osseo-integratie werden voorzien van drukknoppen (ball anchors) en een overkappingsprothese. De patiënt tevredenheid werd 2 maanden na het plaatsen van de overkappingsprothese opnieuw beoordeeld met wederom hetzelfde vragenformulier. Er was een significante verbetering voor wat betreft de tevredenheid over alle onderzochte aspecten van de implantaat gedragen overkappingsprothese ten opzichte van de conventionele prothese ($p<0.05$).

Het vervaardigen van alleen een conventionele prothese verbeterde de patiënt tevredenheid voor bepaalde factoren (fysieke pijn, psychologisch ongemak, handicap, reinigbaarheid, comfort en esthetiek).

Aspecten zoals functionele beperking, psychisch ongemak, fysieke en sociale handicap, algemene tevredenheid, spraak, stabiliteit en kauwvermogen waren voor de implantaat gedragen overkappingsprothesen statistisch significant verbeterd ($p<0.05$).

Uit deze studie werd geconcludeerd dat een implantaat gedragen overkappingsprothese op 2 implantaten met drukknoppen in de bovenkaak de kwaliteit van leven op korte termijn significant verbetert.

De houvast van een overkappingsprothese is een essentieel criterium voor de patiënt om zich tevreden en comfortabel te voelen bij spreken en bij het dagelijks functioneren.

De bedekking van beide tuberantia in de bovenkaak blijkt een belangrijker rol te spelen dan bedekking van het palatum als het gaat over de retentie van een overkappingsprotese in de bovenkaak (Orstavik & Floystrand 1984). Een studie van overkappingsprothesen in de bovenkaak op 4 implantaten met stegconstructie gaf geen significante verbetering bij het wel of niet bedekken van het palatum (de Albuquerque Junior et al. 2000).

In hoofdstuk 4 van dit proefschrift wordt besproken of bedekking of vermindering van bedekking van het palatum een verschil maakt over de tevredenheid van de patiënt bij een overkappingsprothese op 2 implantaten met drukknoppen.

Dezelfde patiënten groep als in hoofdstuk 3 kreeg 2 maanden lang een implantaat gedragen overkappingsprothese op 2 implantaten met drukknoppen en bedekt palatum. Hierna werd gevraagd het OHIP-20 E formulier in te vullen en werd er aanvullend gevraagd naar reinigbaarheid, algemene tevredenheid, spraak, comfort, esthetiek, stabiliteit en kauwvermogen. Na deze 2 maanden werd het palatum van de prothese gereduceerd tot het metalen frame van de overkappingsprothese en werden de prothesen gepolijst. Na 2 maanden functioneren met de “gereduceerde“ prothese werd wederom gevraagd de bovengenoemde vragenlijst in te vullen. De vergelijking van de overkappingsprothese met- of gereduceerd palatum leverde dezelfde patiënt tevredenheid op voor alle OHIP items. Patiënten met gereduceerd palatum van de overkappingsprothese waren significant meer tevreden over esthetiek en smaak ($P<0.01$). Concluderend kunnen we zeggen dat het wel of niet reduceren van het palatum van de overkappingsprothese de patiënt tevredenheid niet beïnvloed. In individuele gevallen is het echter wel te overwegen het palatum van de overkappingsprothese te reduceren ten gunste van de esthetiek, smaak, fonetiek en kokhalsreflex.

Diverse systematische reviews hebben de vraag onderzocht wat het ideale aantal implantaten is voor retentie van een overkappingsprothese in de bovenkaak (Gallucci et al. 2009; Kern et al. 2016; Klemetti 2008; Roccuzzo et al. 2012; Sadowsky 2007; Slot et al. 2010). Er was onvoldoende wetenschappelijk bewijs daar een goed antwoord op te geven. Vanuit het klinisch perspectief zijn overleving van implantaten met prothese, marginale botniveau's, biologische en technische complicaties bepalend voor het succes van een implantologische behandeling. Het is algemeen bekend dat implantaat verlies meestal optreedt binnen het eerste jaar na plaatsing, early failure, voor osseointegratie van het implantaat (Esposito et al. 1998). Minder dan 50% van het verlies van implantaten zijn zogenaamde "late failures", implantaatverlies waar ondanks initiële osseo-integratie deze in de loop van de tijd verloren is gegaan. Om deze reden is in hoofdstuk 5 de overlevingskans onderzocht 1 jaar na plaatsing van de 2 implantaten bij de implantaat gedragen bovenprothese, hierbij werden eveneens botverlies, biologische- en technische complicaties onderzocht. De aangepaste of nieuw gemaakte prothesen werden hierbij gebruikt als sjabloon voor vervaardiging van een gestandaardiseerde CBCT scan (NewTom 5G, QR, Verona, Italië) en voor vervaardiging van de chirurgische boormal. Ook werden van deze prothesen barium sulfaat houdende duplicaat modellen gemaakt welke werden gemodificeerd en geschikt gemaakt voor de implantaat planning software (coDiagnostiX, Dental Wings Inc. Montreal, Canada). Daar waar mogelijk werden de implantaten op de hoektandpositie geplaatst, kleine botaugmentaties werden toegestaan als dit de stabiliteit van het implantaat niet beïnvloedde. In verband met de vaak kleine botvolumes op de hoektandposities is gekozen voor twee smalle diameter titanium-zirconium implantaten (Roxolid® Tissue Level, 3.3 mm diameter, Regular Neck, Instituut Straumann AG, Basel, Zwitserland). Omdat het geen verschil maakt voor de implantaatoverleving als deze 1- of 2-fase worden geplaatst (Astrand et al. 2002; Ericsson et al. 1997) werden beide methoden toegepast. Na 3 of 5 maanden genezing, afhankelijk of er een botopbouw heeft plaatsgevonden, werden er drukknoppen geplaatst en werden de overkappingsprothesen met bijbehorende matrixen geplaatst. Patiënten werden onderzocht 1, 2, 4 en 8 weken na plaatsen van de implantaten en 2, 4 en 12 maanden na het plaatsen van de overkappingsprothese (baseline). Intra orale röntgenfoto's werden op een gestandaardiseerde manieer vervaardigd met individueel gemaakte mallen op het moment van belasten van de implantaten en na 1 jaar. Bij een gemiddelde evaluatietijd van 1.1 jaar (spreiding 1.0-1.7 jaar) werden 19 patienten en 38 implantaten geëvalueerd (1 patiënt is afgevallen). De overlevingskans van de geplaatste

implantaten bedroeg 97.3% waarbij 1 implantaat verloren is gegaan. Na 1 jaar was er significant botverlies (gemiddeld 0.7 mm, SD 1.1 mm, mediaan 0.48 mm, IQR 0.56 mm). Er was meer dan 2 mm botverlies opgetreden rond 8% van de implantaten. In totaal zijn er 13 zachte weefsel problemen geweest tijdens de onderzoeksperiode, rond 11 implantaten (29%) bij 8 patiënten was er sprake van hypertrofie van de gingiva, 1 drukplaats en 1 recessie. De technische complicaties die optraden waren 4 kleine en 2 grote fracturen van de prothesetanden en in 6 gevallen moest er een rebasing worden uitgevoerd. Ondanks deze verschillende complicaties en toenemend botverlies was de 1 jaars implantaatoverleving hoog. Op basis van de resultaten van dit onderzoek kan het plaatsen van 2 implantaten op de hoektandposities als steun voor een overkappingsprothese in de bovenkaak niet worden aanbevolen als standaard behandeling.

Langere en meer follow-up studies over dit onderwerp zijn noodzakelijk om over deze behandelmodaliteit voorspelbaar uitspraken te kunnen doen. In specifieke gevallen zou bij een aantal geselecteerde patienten deze minimaal invasieve procedure een goed alternatief kunnen bieden.

Een belangrijk onderwerp dat in dit proefschrift werd behandeld is de beoordeling van de tevredenheid van de patiënt met behulp van vragenlijsten voorafgaand aan de behandeling, wat een belangrijke factor was bij beoordeling van de tevredenheid na de behandeling. Voordat de implantaten werden geplaatst werd de bovenprothese door de geïncludeerde patiënten beoordeeld. Een evidence based review van PROM's (patient-reported outcome measures) bij implantaatonderzoek laat zien dat bij veel van deze studies alleen na behandeling een tevredenheidsonderzoek wordt uitgevoerd. Het voordeel van behandeling wordt dan niet vergeleken en kan zo niet worden aangetoond (McGrath et al. 2012). Retrospectieve tevredenheidsonderzoeken door patienten zeggen meer over het herstel van een gebeurtenis, vooral wanneer dit onderzoek wordt uitgevoerd kort na een ingreep. Dit heeft ook de beperking dat mensen vooringenomen kunnen zijn, recall bias effect (Locker et al. 2004). Er wordt daarom aanbevolen PROM's te beoordelen met een follow-up van een jaar of langer (McGrath et al. 2012).

In hoofdstuk 6 werd de patiënt tevredenheid vergeleken tussen baseline en 1 tot 4 jaar na behandeling. Er werd verder onderzocht of het aanvankelijke voordeel van de implantaatbehandeling bij de patiënt over langere tijd zou blijven bestaan. Na aanbieden van zowel een overkappingsprothese met- en zonder palatum bedekking (hoofdstuk 4) mochten patiënten aangeven welke prothese de voorkeur had. Tweederde (16

patiënten) gaf de voorkeur aan voor verminderde palatinale bedekking. Eén derde (5 patienten) verzocht om palatinale afsluiting. Na 4 jaar was de score voor sociale handicap het hoogst en functionele beperking het laagst. De tevredenheid van de patiënt veranderde niet significant voor geen van de OHIP items na 1 en 4 jaar ten opzichte van baseline, waarbij de tevredenheid van de patiënt over de overkappingsprothese door 2 implantaten ondersteund onveranderd bleef.

Om een behandelconcept voor te stellen waarbij er 2 implantaten worden geplaatst op de posities van de cuspidaten in de edentate bovenkaak voor een overkappingsprothese, moeten de patienten waar dit is uitgevoerd over een aantal jaren worden gevolgd.

Hoofdstuk 7 onderzocht de implantaatoverleving, peri implantair botverlies en de incidentie van biologische en technische complicaties na 4 jaar. Vijftien patiënten (10 mannen, 5 vrouwen) zijn gemiddeld 4 jaar vervolgd (spreiding 3.3-4.2 jaar). Zes implantaten zijn verloren gegaan bij 5 patiënten (3 mannen, 2 vrouwen). Eén patiënt verloor beide implantaten. De Kaplan Meier implantaat overlevingskans was 75%. In vergelijking met baseline was er na 4 jaar significant marginaal botverlies (gemiddeld mesiaal 0.9 mm, SD 1.5 mm, gemiddeld distaal 1.0 mm, SD 1.3 mm, mediaan mesiaal 0.8 mm, mediaan distaal 0.6 mm, IQR mesiaal 1.7 mm, distaal 1.3 mm). Vier jaar na baseline was er mucositis aantoonbaar rond 1 implantaat, verder werden er geen biologische complicaties gevonden.

Betreffend de technische complicaties na 1 jaar tot de laatste controle na 4 jaar bleken er 17 matrixen mobiel bij 10 patienten (9 mannen, 1 vrouw). Dertig metalen veren van de matrixen waren of verloren of gebroken bij 7 patiënten en zijn vervangen. Eén complete matrix was verdwenen en werd vervangen. Twee fracturen van prothesetanden werden gezien bij 2 patiënten en bij 2 patiënten was een rebasing noodzakelijk.

Acknowledgements

Starting in chronologic order, first and foremost I thank my wonderful parents **Dr. med. Nikola and Tijana Zembic** for giving me the opportunity to study dentistry and for their tremendous love. Without them none of this would have been possible. My parents and family never gave up “reminding” me of my PhD. They always believed in me and supported me to achieve the things I started.
Hvala premili mapala za sve, obozavam vas!

Secondly, abundant love and thanks to Neni, **Prof. Dr. Irena Sailer**, who is much more than a loving sister to me. She often guided me when I started losing focus and is my personal mentor. Thanks to Irena I started my academic path at the university of Zurich, Switzerland, after working 2.5 years in a private practice in Germany. I was not aware that this was the beginning of a wonderful journey and the first step into my dental career. Irena always motivated me, even in the final steps of this thesis. The best she could do was to convince me to join their “work camp” in Iceland, where she was writing a book with Bjatni and Vincent. This atmosphere was very constructive and helpful for me to finish my thesis. Thank you, Irena, for everything and for being my para-nymph.

Thirdly, I would like to thank cordially **Prof. Dr. Christoph Hämmerle**, my co- promoter, the best teacher and a very special boss. Christoph influenced my academic development significantly. He was the one who suggested to apply for an ITI scholarship, after finishing my postgraduate program in his clinic at the university of Zurich. Thanks to Christoph I learned a structured approach when planning a study and setting up the study protocol. With his profound knowledge and experience, Christoph taught me how to perform proper research, which was the foundation for my research project in Amsterdam. Christoph also supported me to finish the thesis while being back in Zurich, which I can`t thank him enough for.

Huge thanks to my promoter and second extraordinary boss **Prof. Dr. Daniel Wismeijer**. Daniel welcomed my coming to his ITI scholarship center and had confidence in me, so I could perform the surgeries on my own. This was a meaningful step into my professional independence, after finishing the postgraduate program. He

gave me a lot of freedom to make my own choices, while always supporting me in moments, where I needed his advice. Thanks to Daniel, I was able to perform autonomous research from scratch. After patient recruitment and the preparation of patients in terms of a prosthodontic pre-treatment, my scholarship was over. Luckily, Daniel gave me the great opportunity to stay for another 2 years employed at his department, so I could finish all patient treatments and part of the publications. Daniel also recommended the PhD, which to me was and still is a very nice appreciation of my work. Whenever I wrote an email to him, I could be certain to get an immediate response. But also, with regard to other issues concerning the PhD, Daniel was always fast, efficient and helpful. I value Daniel not only as great mentor and promoter, but also personally very much.

Further cordial thanks go to **Prof. Dr. Ronald Jung** for his efforts in advising me on the kind of project I could work on during my scholarship. Rony took the time to discuss different study ideas with me, which I appreciate so much. This was a perfect preparation for the scholarship, and we could suggest these study ideas to Daniel at the EAO in Monaco 2009. For this purpose, Rony organized a meeting, where I could meet Daniel and Ali a few months before my scholarship started.

Many thanks to **Dr. Ali Tahmaseb, PhD**, my second co-promoter for his support with the digital implant plannings and assistance in the surgeries of the study patients. I appreciate his easygoing and good-humoured nature, which made working with him very pleasant. He was very fast in making decisions and helping me out, whenever I needed him.

I would also like to express my gratitude to **Straumann** for the support with the implant materials (implants, abutments, device for digital implant planning). This device (GonyX^{TM}) was by that time not even available on the Dutch market, so Sandro Venanzoni and colleagues from Straumann came specifically to ACTA to bring the device and give us a demonstration and hands-on course, how to use it properly. The supply with study material was always generous, smooth and well-organized, so that I had the best possible conditions to work at the patients.

Special thanks go to **Michel Mallaun, PhD** from Straumann, my study monitor and good friend, for supporting my mission and appreciating my commitment to this research. Being a PhD himself, he could give me good advice from his own experiences. He was also very interested in the clinical part of the study, which was the basis for interesting discussions. It was a pleasure for me to work and share thinking out of the box with him.

Great thanks go to all my supportive **study patients**, who agreed to participate in this research and accepted that I did not speak Dutch in the beginning. After I learned Dutch, another world opened up to me and I will never forget, when one of my patients told me, that he always thought, I would be a dental student, while I already had performed the implant surgery in him. This still impresses me today and I perceived all my ACTA patients as being relaxed and very nice people to cooperate with. They often had to come back for several treatments and controls, and I appreciate their sense of duty by regularly showing up to these appointments.

Many thanks to the **ladies from the implantology department at ACTA**, especially:

- **Carmen**, who was very well organized and took care of my valuable study material. She always found a solution for everything, especially, when i needed a dental chair or assistant on short notice, what i am very grateful for.
- **Elaine**, who organized all my appointments with my study patients and helped me out in the administrative part, when I applied the implant surgeries to the insurances.
- **Jaqueline** for scheduling and rescheduling my patients and always being calm, professional and kind.
- **Inge** for taking care of the appointments with my study patients in the old ACTA and referring a friend of her to me, who became a study patient.
- **Els**, for helping me out with all administrative and general concerns.
- **Eva**, **Hannah**, **Sylvia** and **Dieuwke** for their assistance and help, when i stressed them in the clinic.

Further giant thanks to the always kind and very helpful people from the **radiology department at ACTA: Bassam Hassan, PhD, Dr. Gerard Sanderink, Dr. Kostas Syriopolous, Agnes and Mieke**. All the patients who met the inclusion criteria underwent a CBCT scan pre-operatively, post-operatively and at 1 year. I accompanied

the patients to insert the templates, before the scans were performed. After the scan I received the data immediately transferred to a CD-ROM. Bassam, Gerard and Kostas did a great job to go through the data with me in challenging anatomical situations, to ensure a proper reading of the data. After some time, everybody knew the special procedure with “Anja`s onderzoekspatienten” and we were a well-rehearsed team.

For the CBCT scans and implant plannings, specific templates were needed. These were fabricated together with conventional dentures and implant overdentures by **Martin Bub, master dental technician and** his **team** from dental laboratory Zutphen. I was very satisfied with our good collaboration and the high-quality prosthodontics.

Adjustments of dentures, repairs and the translation from dentures without palatal coverage to dentures with palatal coverage (which was part of this thesis) were executed in the internal dental laboratory of ACTA by **master dental technician Jeff Liem and Michel Voogd**. These in-house adjustments were a great benefit for the patients. Huge thanks to both Jeff and Michel for their support and meticulous efforts.

I would like to thank the **International Team for Implantology ITI** for supporting my scholarship 2009 – 2010 at the Section of Implantology and Prosthetic Dentistry at ACTA. I thereby received the opportunity to become part of a huge dental community with a lot of similar minded colleagues from all over the world. What started as ITI scholarship is ending now with this PhD thesis, which is a fantastic closure of this chapter for me.

Additional thanks to all teachers and instructors at the implantology department during my time: **Prof. Dr. Rien v. Waas, Jeroen Huigen, Gordon v.d. Avoort, Pieter v. Elsas, Enrique Rikken, Johan Cosse, Erik Blom, Haakon Kuit, Jan Wilem Wolf, Bea Gimenez, Annechien Scheygrond and Sanja Umanjec Korac**.

In the beginning, most people did not know, what an ITI scholar is about. Being at the department for more than 3 years clarified these concerns and today we share a lot of nice stories and memories with each other.

Many thanks to the TIO`s (postgraduate students) from the implantology department: **Lilian, Brampieter, Dan, Ruud, Linde, Frank, David, Adina, Pepler, Wiebe, Paul and Cristina**. It was fun to share the office with them and go for an after-work drink in the bar of the old ACTA, which reminded me of the one in Grace Anatomy. In the beginning I did not understand a word when they discussed patient cases in Dutch. But this was an interesting experience and big motivation for me to learn Dutch.

After a while, I had to move out of the office with the TIO`s and share the office with **Dr. Joep Laverman**. This was a perfect timing, because in this phase I already started writing the publications and was less involved in patient treatments. Thus, I appreciated the silence in his room, which helped me concentrate better when reading and writing. It was always fun with Joep`s special humor and we became great office partners. I enjoyed our tradition of going for a coffee downstairs at the bar in the entrance hall.

Cordial thanks to my close friends from Iceland **Prof. Dr. Bjatni Pjetursson and Dr. Kristin Heimirsdottir** for welcoming me in their adorable farm house in Hjardartun, where I could finish the writing of this thesis. The beautiful scenery but also the wonderful Icelandic horses, with Bakkus in particular, contributed to my creativity in the writing process.

Many thanks to **Drs. Linde v. Groningen and Johan Cosse** for the meticulous help with the Dutch summary and with organizing the addresses and phone numbers from all the previous colleagues for me.

Cordial thanks to **Ceylin Tastepe**, **PhD** for her mental support and for being such a great friend. We met in the old ACTA and immediately connected. This was in the beginning of her and my PhD. I am looking forward to having her as para-nymph.

Special thanks to my cousin **Anika Zembic**, who checked the reference list of this thesis for completeness. That she did a precise job was evident, when she asked me, whether it is right that there is a “Mo et al. 2016” and a “Ma et al. 2016“, which indeed was correct.

Further estimated thanks to **Prof. Dr. Esam Tashkandi** for his time and effort to read my thesis and give me honest and impartial feedback.

Great thanks to **Gisela Müller**, **MSc** for organizing the references of the publications in the style of the particular journals and for helping me to merge the publications and thesis to one PDF document. Not only that Gisi is very precise and reliable in whatever she is doing, she also saved so much of my time and efforts. Whenever I had a question that I felt Gisi could know, she would immediately help me out in her friendly, structured and uncomplicated way.

Great thanks to **Antonella Tepedino, Dental hygienist,** for her fantastic and altruistic help during a late-night shift in the clinic with the editing of the complete manuscript in the very last minutes before printing. This meant and still means so much to me.
Molte grazie mia cara Anto!

Lots of thanks to **Daniel Wiedemeier**, **PhD** (statistician University of Zurich) for his kind help and coaching with the statistics.

Thanks also to **Martijn v. Steenbergen**, **research coordinator ACTA** for his support in the PhD process. Whenever i had a question via email or phone, Martjin did his best to immediately help me.

I kindly thank **all reviewers** for their time, efforts and expertise when evaluating this thesis.

Sincere thanks to the **dean Prof. Dr. Albert Feilzer** for the good discussion during the interview in Zurich and his interest in my research topic.

I thank the **Academisch Centrum Tandheelkunde Amsterdam ACTA** for the funding of the printing of this thesis.

Curriculum Vitae

Anja Zembic, PD Dr. Med. Dent.

Date of birth: 21. April 1974

Place of birth: Albstadt, Germany

Address for correspondance:
University of Zurich
Center of Dental Medicine
Clinic of Fixed and Removable Prosthodontics and Dental Material Science
Plattenstrasse 11
CH-8032 Zurich

anja.zembic@zzm.uzh.ch

Education

1984 - 1993	High school (Gymnasium) in Albstadt-Ebingen, Germany
1993 - 1999	Studies in General Dentistry, Faculty of Medicine, Eberhard-Karls University of Tübingen, Germany
2002 - 2003	Postgraduate Student at the Clinic for Oral Surgery, Department of Oral and Maxillo-Facial Surgery, University of Zurich, Switzerland (Chairman: Prof. Dr. Dr. K.W. Grätz)
2006 - 2009	Postgraduate Student at the Clinic for Fixed and Removable Prosthodontics and Material Science, University of Zurich, Switzerland (Chairman: Prof. Dr. C.H.F. Hämmerle)

Certifications, Titles and Awards

1999	State examination and Diploma for Dentist (med. dent.), University of Tübingen, Germany
2004	„doctor medicinae dentium“ (Dr.med.dent.), (magna cum laude), University of Tübingen, Germany
2005	Award for the best presentation: “Randomized controlled clinical trial of customized zirconia and titanium implant abutments for posterior single- tooth implant reconstructions: Preliminary results

	at 1-year of function." in Luzern, Switzerland from the Swiss Society for Implantology (SGI)
2013	Basic of university didactic (3-day course)
2014	Specialist for reconstructive dentistry SSO/SSRD
2015	Good Clinical Practice, Modules 1 & 2
2016	Good Clinical Practice, Modules 1 & 2
2016	Venia Legendi (Privatdozent, PD) in the fields of Fixed reconstructions on dental implants, Faculty of Medicine, University of Zurich, Switzerland
2016	European Prosthodontic Association (EPA) Recognised Specialist
2016	Award for the best publication in the field of implantology "Within-Subject Comparison of Maxillary Implant-Supported Overdentures with and without Palatal Coverage" in Den Haag, The Netherlands from the Dutch Society for Implantology (NVOI)
2018	Basic training in dental hypnosis (courses 1 &2)

Principal Positions Held

2000 - 2002	Associate in a private practice in Germany (Dr. E. Fessler, Frickenhausen)
2002 - 2003	Postgraduate student at the Clinic for Oral Surgery, Department of Oral and Maxillo-Facial Surgery, University of Zurich, Switzerland (Chairman: Prof. Dr. Dr. K.W. Grätz)
2003 - 2005	Associate in a private practice in Switzerland (Swiss Dental Center, Zurich)
2004 - 2006	Research fellow at the Clinic for Fixed and Removable Prosthodontics and Material Science, University of Zurich, Switzerland (Chairman: Prof. Dr. C.H.F. Hämmerle)
2005	Associate in private practice in Switzerland (Dr. O. Kalkstein, Affoltern a. Albis)
2006	Associate in private practice in Switzerland (A. Dubiel, Fehraltorf)
2006 - 2009	Postgraduate student at the Clinic for Fixed and Removable Prosthodontics and Material Science, University of Zurich,

	Switzerland (Chairman: Prof. Dr. C.H.F. Hämmerle)
2009 - 2010	ITI Scholar at the Department of Oral Implantology and Prosthetic Dentistry, Academic Center for Dentistry Amsterdam (ACTA), The Netherlands
2010 - 2012	Research fellow and associate at the Department of Oral Function, Section of Oral Implantology and Prosthetic Dentistry, Academic Center for Dentistry Amsterdam (ACTA), The Netherlands
2012 - 2014	Senior teaching and research assistant at the School of Dental Medicine, Division of Fixed Prosthodontics, University of Bern (ZMK Bern), Switzerland
2016	Award for the best publication in the field of implantology "Within-Subject Comparison of Maxillary Implant-Supported Overdentures with and without Palatal Coverage" in Den Haag, The Netherlands from the Dutch Society for Implantology (NVOI)
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2005	Associate in private practice in Switzerland (Dr. O. Kalkstein, Affoltern a.Albis)
2006	Associate in private practice in Switzerland (A. Dubiel, Fehraltorf)
2006 - 2009	Postgraduate student at the Clinic for Fixed and Removable Prosthodontics and Material Science, University of Zurich,

	Switzerland (Chairman: Prof. Dr. C.H.F. Hämmerle)
2009 - 2010	ITI Scholar at the Department of Oral Implantology and Prosthetic Dentistry, Academic Center for Dentistry Amsterdam (ACTA), The Netherlands
2010 - 2012	Research fellow and associate at the Department of Oral Function, Section of Oral Implantology and Prosthetic Dentistry, Academic Center for Dentistry Amsterdam (ACTA), The Netherlands
2012 - 2014	Senior teaching and research assistant at the School of Dental Medicine, Division of Fixed Prosthodontics, University of Bern (ZMK Bern), Switzerland
2014 -	Senior Teaching and Research Assistant at the Clinic for Fixed and Removable Prosthodontics and Material Science, University of Zurich Associate in private practice Zahnmedizin Zürich Nord Responsible for the dental education of dental hygienists at Prophylaxe Zentrum Zürich, Höhere Fachschule für Dentalhygiene

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C. A. S. Trilussa